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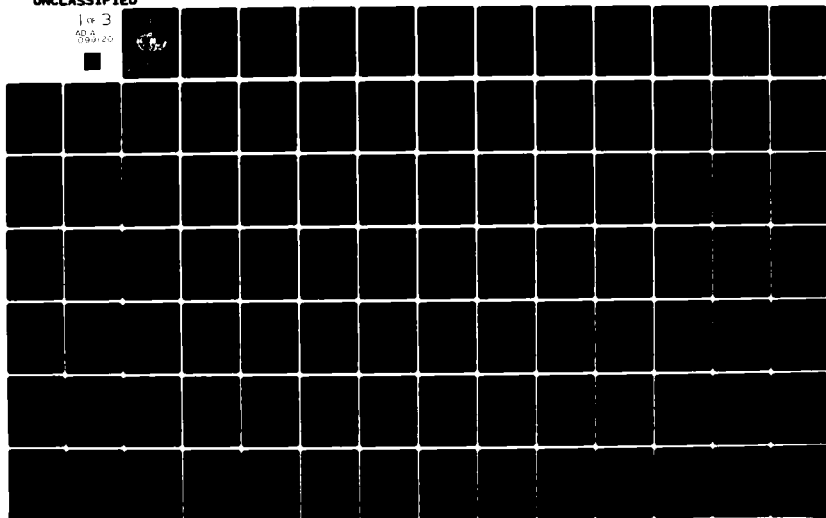
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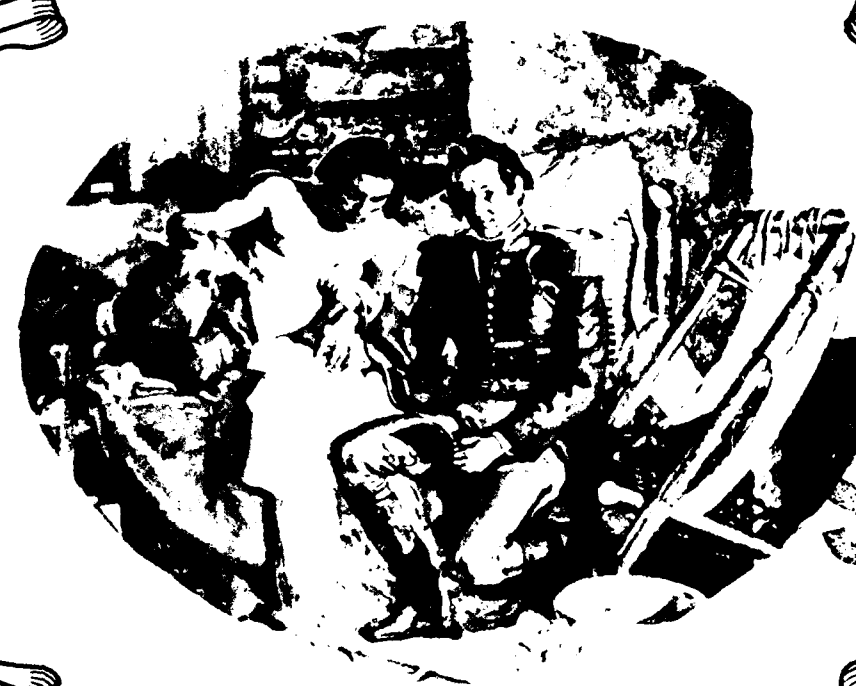


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DEPT. OF CLINICAL INVESTIGATION

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# ANNUAL PROGRESS REPORT FISCAL YEAR 1980

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) This report serves to detail the progress, status, and funding of approved projects conducted under protocol by staff members, interns, and residents at William Beaumont Army Medical Center. The varying projects as reported are classified according to the service or department to which the principal investigator belongs. Research conducted at WBAMC is categorized as either basic experimental medicine or trials and testing of clinical medicine procedures using the indigenous population for which this medical facility provides support.		

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Surgery  
Steroids

## FOREWORD

The Dept Clinical Investigation, formerly Medical Research and Development, is entering its 16th year of operation. Largely through the efforts of COL Norman Ream, MC, Consultant for Clinical Investigation, HSC, and his staff, Departmental status was achieved in FY80. COL Ream and his staff are also to be commended for their efforts in decentralizing the protocol approval process. Monumental gains have been realized in this area.

Personnel shortages and uncertainty persisted, but budgetary progress was realized in FY80. The Department is particularly indebted to BG Kenneth Cass, Commander, WBAMC Jul 1979 - Jul 1980, who recognized the importance of Clinical Investigation and reversed a two-year downward spiral in OMA funding, and who was instrumental in approving construction of a portable building which will greatly expand the training and research capabilities of the Biological Research facility of the Department. The Dept of Clinical Investigation also appreciates the continued support shown by BG Chester Ward, MC, Commander WBAMC, Aug 1980 to the present.

The Department has fulfilled its mission in a productive manner. The investigators who actively pursued their projects, frequently utilizing their own hours from off-duty time and occasionally providing their own funds, are to be especially commended. All investigators for each work unit are identified in the respective reporting sections.

The contributions of the many nurses, technicians, corpsmen and administrative personnel who are vital to the successful implementation of clinical research projects are acknowledged.

I am grateful for the editorial and typographical assistance of Ms Peggy Casteel in the completion of this document and to the remaining staff of the department for their varied areas of contribution.

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*L.L. Penney*  
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COL, MC  
C, Dept Clinical Investigation

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## UNIT SUMMARY

### OBJECTIVES

The Department of Clinical Investigation, William Beaumont Army Medical Center, was established 2 February 1965 as the Medical Research and Development Service. The mission is to promote and coordinate clinical research and directed basic research. The policies and objectives are outlined in Department of Defense Directive Number 6000.4 dated 7 April 1971:

"Clinical investigation is an essential component of optimum medical care and consists of the organized inquiry into clinical health problems, for the following purposes:

1. To achieve continuous improvement in the quality of patient care.
2. To provide experience in the mental discipline achieved by participation in such organized inquiries, and to provide experience for personnel who will ultimately be teaching chiefs in military hospitals and medical specialty consultants.
3. To maintain an atmosphere of inquiry because of the dynamic nature of the health sciences.
4. To maintain high professional standing and accreditation of advanced health education programs."

The Department supports in-house research projects by AMEDD staff members, residents, and interns, assisting in the formulation, preparation, and promulgation of research protocols and final research publications. The Department furnishes experimental design and statistical and technical expertise, develops and carries out special laboratory procedures, and provides general support in terms of equipment, supplies, and animal resources when necessary. The creative and inspirational environment and technical knowledge available serve to stimulate the undertaking of basic and clinical medical and paramedical research at William Beaumont Army Medical Center by staff members, and interns and residents in training, as well as provide a basic instructional facility to elucidate the principles and conduct of research.

In addition to the primary mission, as stated above, the Department is active in supporting several training and teaching programs involved with direct patient care. As examples, H.T. Klenke conducts a year-long health physics course supplemented with statistical review for the Nuclear Medicine Fellowship, and the Department participated in a three-month formal lecture series on radioimmunoassay. The Biological Research Facility directly supported approximately 450 anesthesia and surgical assistance training procedures ranging from minor suturing techniques for the Clinical Specialist Course students through aortic bypass grafts for the surgical residents. Examples of formal training protocols supported by the department are detailed in Appendix 1.

The department has provided scientific and administrative computational support to the Department of Nursing, Pathology, Medicine, Surgery, and Logistics Division of WBAMC. The department provides this support as it alone possesses unique skills and equipment necessary to perform the tasks. The tasks may require mathematical modeling, statistical analysis, or graphical representations. The specific support provided FY80 is as follows:

Nursing requested statistical verification of workload data collected in a proper manner. An automated infectious control program is being considered.

Logistics has been provided with programs to maintain its MEDCASE program, the purchasing program for the Bradley Annex under construction, linen control program, and expendable item control program.

The Department of Medicine required statistical analysis of data for presentation and programs were written to capture and evaluate such data.

In addition, all radioimmunoassay calculations and reports performed by Nuclear Medicine were done utilizing equipments and programs provided by the Department of Clinical Investigation

#### TECHNICAL APPROACH

The Dept of Clinical Investigation provides support for staff research projects under the guidelines of the Declaration of Helsinki, Clinical Investigation Program (AR 40-38), and the Use of Investigational Drugs in Humans and the Use of Schedule I controlled Drug Substances (AR 40-7). Research is conducted under protocols approved by the Research Committee (WBAMC HR 70-4), the Human Use Committee (WBAMC HR 40-38) and the Radioisotope Committee (WBAMC HR 40-37) where applicable. Following at least three years of discussions, conferences, and debates at the Annual Clinical Investigation Conferences, as well as various interval communications, HSC Regulation 40-23 was drafted in final form. The Commander, HSC, MG Marshall McCabe, approved the regulation "Management of Clinical Investigation Protocols and Reports" and it was implemented 28 Dec 79. This regulation represents a significant change of policy in the recognition of local expertise, authority and responsibility. It decentralizes the approval process for several categories of protocols. Further decentralization seems appropriate. In those research protocols utilizing laboratory animals, the investigators follow guidelines set forth in "Guide for Laboratory Animal Facilities and Care," published by the Committee on the Guide for Laboratory Animal Facilities and Care of the Institute of Laboratory Animal Resources, National Academy of Sciences-National Research Council, and the criteria established by the American Association for Accreditation of Laboratory Animal Care.

# MANPOWER

Title	SSI/MOS	Auth	Assigned	Name
Chief	60J	0-5	0-5	Penney, Larry L., MC
Nuc Med Sci/ Admin Off	68B	0-3	0-2	Klenke, WJ, MSC
Biochemist/ Asst Chief	68E	0-3	0-4	Sellers, M.E., MSC
Vet Lab Animal Off	64C	0-3	0-3	Parker, G., VC
Med Lab Sp	01H20	E-5	E-6	Robinson, Bryan
Vet Anim Spi	91T20	E-3	E-4	Lee, Daniel F
Vet Anim Sp	91T10	E-3	E-4	Graf, James P
Vet Anim Sp	91T10	E-3	E-4	Lipp, Gary
Vet Anim Sp	91T10	E-3	E-4	Revels, Scott
Hlth Tech	00699	GS-7	GS-7	Revels, J.F.
Ann Res Asst				
Ann Caretaker	07706	WG-3	WG-1	Burton, A.D.
Chemist	01311	GS-11	GS-11	Rauls, D.O.
Microbiologist	00403	GS-11	GS-11	Frederick, R.
Chemist	01320	GS-9	GS-9	Sandison, S.W.
Chemist	01320	GS-9	GS-9	Meyers, T.
Med Lab Tech	00645	GS-7	GS-7	Manna, B.S.
Med Lab Tech	00645	GS-7	GS-6	Abshire, T.
Editorial Asst	01087	GS-7	GS-7	Casteel, P.J.
Med Lab Sp	01H20	Recognized Requirement - Not Authorized		
Vet Ann Sp	91T10	"	"	"

EXPENDITURES	FY77&7T	FY78	FY79	FY80
Personnel (Civilian)	148,153	118,995	151,769	171,444
Consumable Supplies	56,831	35,923	34,392	60,134
MEDCASE Equipment	48,324	33,169	37,333	140,868*
Capital Equipment	-	-	2,425	10,427
TDY	3,485	2,805	1,179	1,469
Contracts, Services, Printing and Reproduction	4,327	3,053	937	1,025
TOTAL	\$261,120	\$193,945	\$228,035	
Military Pay			141,385	167,437
			\$369,420	\$556,272

The actual MEDCASE expenditure was about \$82,000. Approximately \$58,000 of the above total was paid in FY80 for equipment received in FY79. (See FY79 Annual Progress Report). The Dept Clinical Investigation further accounted the supply expenditures into general office, \$3116; general laboratory (divided among two or more protocols or for maintenance, standards, etc), \$18,189; and general biologic research facility (primarily training protocols) \$13,851. The remaining \$25,028 was spent on 21 specific protocols and the amount is noted under consumable supplies on the appropriate detail sheets.



It is impossible to account equipment, personnel, TDY and general supplies to specific protocols. However eliminating terminated protocols there were 99 active protocols in FY80. The following figures will be high estimates because a portion of personnel, supply, and equipment expense is for training as opposed to research. Furthermore all of the salary for the C, Dept Clinical Investigation is accounted here and a portion of his time is actually spent in patient care and teaching.

Comptroller data listed above \$556,272 indicates an overall average of \$5619 total expenditure per active protocol. Several of the older protocols received more limited funding in deference to those more current. It is also important to note that a large clinical study, with little or no equipment or laboratory expense, can be quite costly in terms of personnel for administration, data collection, and reduction, committee preparation, annual review, HSC and OTSG coordination and manuscript preparation. The average personnel cost for these services exceeds \$500 per protocol for the WBAMC, DCI. Partly due to the avalanche of regulations and increasing numbers of forms, minutes, etc., which must be maintained and distributed, the supply cost for paper, clips, staples, folders, and other strictly administrative materials have risen to an average of \$31 per protocol per year.

TDY for minimal continuing education and mission-essential training was granted. The department provided no TDY trips for any investigator to present findings at professional meetings.

The department had two recognized requirements unfilled in FY79, but all authorized positions were filled. The modest increase in numbers of protocols accepted and completed, and in publications and presentations attest to the value of stabilization as noted in the FY78 report. Stabilization of principal investigators continues to be a problem as witnessed partially by the number of terminated protocols.

PROGRESS: During this fiscal year WBAMC authors had 63 articles or presentations published or accepted. Eleven new submissions and seven previously reported submissions are still pending. A tabulation of pertinent workload and dispositions compared to budget (not adjusted for inflation) for the past five years follows: (FY77&78 have been combined, but adjustment to 12 months is shown in parenthesis)

	Protocols Ongoing at start FY	New Protocols Submitted During FY	Total Protocols	Protocols Completed During FY	Protocols Terminated During FY	Publications and Presentations	OMA Budget
FY76	49	32	81	12	16	48	\$20,471
FY77 & 7T	53 (42)*	25 (20)	78 (62)	18 (14)	15 (12)	24 (19)	\$56,831 (\$45,465)
FY78	45	30	75	3	9	28	\$35,923
FY79	63	43	106	9	14	46	\$34,392
FY80	83	41	124	25	25	63	\$60,134
FY81	74						

\*Figures in parentheses represent adjustment to a base of 12 months.

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Normal Values of Serum Triiodothyronine (T3) as Determined by  
Radioimmunoassay in Various Clinical Euthyroid States

WORK UNIT NO: 75/07

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MD; Douglas Daniels, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Determine normal values of T3 for: (a) Pregnancy during all three trimesters. (b) Females taking oral contraceptives. (c) Euthyroid Hashimoto's Disease. (d) Other thyroiditises.

TECHNICAL APPROACH

Serum samples will be obtained from patients during 1st, 2nd, and 3d trimester of pregnancy; females on oral contraceptives for at least three months; euthyroid patients with Hashimoto's thyroiditis before treatment with thyroid hormone and after treatment with Synthroid; patients with thyroiditis (subacute). Clinical histories will be obtained and the clinical thyroid state will be determined. The serum samples obtained will be evaluated by radioimmunoassay. Determination of the inclusion into the proposed categories will be from clinical diagnosis, clinically determined thyroid state and appropriate laboratory studies.

PROGRESS

Papers have been published in Clinical Nuclear Medicine reporting studies of T3 values in pregnancy and in patients with chronic renal failure on dialysis. No further studies have been conducted and none are anticipated in the near future.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Isolation and Purification of Choline Phosphotransferase

WORK UNIT NO: 75/30

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To develop a method for the isolation of choline phosphotransferase from lung tissue and correlate respiratory distress with the presence and specific activity of this enzyme.

TECHNICAL APPROACH

Microsomal and lysosomal fractions of lung tissue will be subjected to standardized enzyme purification techniques. Cofactor effects will be studied in order to assess possible prophylaxis development in cases of respiratory distress.

PROGRESS

A manuscript was reported last year. Additional specimens were collected in FY80, but analysis to date is incomplete. Further work will be reported and funded under protocol 77/25.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Penicillin Alone vs Ampicillin and Gentamicin in the Treatment  
of Group B Streptococcal Sepsis

WORK UNIT NO: 78/15

PRINCIPAL INVESTIGATOR: Robert Frederick, PhD, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the in vivo and in vitro killing rates of these antibiotics.

TECHNICAL APPROACH

Scintillation counting will be used for in vitro studies. Serial blood cultures will be used for in vivo studies with a rabbit model.

CONSUMABLE SUPPLIES

\$510

PROGRESS

The clinical isolates used in these experiments have been shown to be "tolerant" to penicillin at 100 to 500 times the minimal inhibitory concentration of the antibiotic. Despite the loss of <sup>3</sup>H glycerol containing cell constituents after treatment with the antibiotic, there appears to be no significant morphological changes in the cell wall or capsular material of surviving cells as seen in electron micrographs. The original principal investigator resigned and the protocol has been continued by the previous associate investigator.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Theoretical and Applied Techniques in Gamma Camera Uniformity  
Quality Control

WORK UNIT NO: 78/21

PRINCIPAL INVESTIGATOR: 1LT W.J. Klenke, MSC

ASSOCIATE INVESTIGATORS: LTC W.F. Kendall, MSC

OBJECTIVES

To develop the theoretical, mathematical basis for defining the separation distance between a gamma camera and a point source for which exposure variations across the face of the gamma camera are reduced to a statistically insignificant level.

TECHNICAL APPROACH

A computer program will be used to calculate the exposure rate at each location on a grid imposed on the face of standard and large crystal gamma cameras for varying separation distances between the point source and the camera. The effect of off-axis alignment of the source will also be evaluated. Experimental confirmation of the computer results will be obtained, using transmission densitometry to measure exposure variations.

PROGRESS

Computer calculations indicated that separation distances between gamma cameras and point flood sources need to be greater than those in general use in clinical nuclear medicine. Results are to be presented at the Southwestern Chapter, Society of Nuclear Medicine. A manuscript has been prepared for submission to the J. Nuclear Medicine.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Efficacy of Active Immunization to Group B Streptococcal  
(GBS) Organisms in Preventing GBS Sepsis

WORK UNIT NO: 78/22

PRINCIPAL INVESTIGATOR: Robert Frederick, PhD, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if active immunity will prevent acquisition of disease and/or prevent and/or blunt the clinical parameters of sepsis.

TECHNICAL APPROACH

A rabbit model is being used in this study. Rabbits are immunized with GBS until they have a "+" CIE to GBS antigen. Once a "+" titer is demonstrated, the animals are injected with both live and killed organisms. CBCs, blood gases, and temperatures are followed closely. If death occurs, histological examination of tissue is being performed.

CONSUMABLE SUPPLIES

\$614

PROGRESS

The experimental portion of this protocol has been completed and the data analyzed. A manuscript is in preparation. The original principal investigator resigned from the Army, and the associate investigator has assumed the study.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Significance Study of meta and para metabolites of  
Catecholamine Compounds in the Rat

WORK UNIT NO: 78/28

PRINCIPAL INVESTIGATOR: MAJ M.E. Sellers, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the significance of meta and para substituted isomers of catecholamine metabolites such as m- and p-tyramine and m- and p-phenylacetic acids by noting changes in isomer quantitation after selective inhibition of the normal metabolic pathway.

TECHNICAL APPROACH

Weanling male Sprague-Dawley rats will be divided into test and control groups. Test animals will be injected with various regimens of catecholamine enzyme inhibitors as well as exogenous L-DOPA. Catecholamines and their acid metabolites will be determined by GC, GC/MS, TLC, etc. As many meta- and para-isomers will be identified, separated, and quantitated as is possible from brain, liver, and urine extracts. The data will be compiled to ascertain whether metabolic inhibition of normal pathways changes the ratios of meta- and para- metabolites and to try to investigate the significance of these changes if they occur.

CONSUMABLE SUPPLIES

\$620

PROGRESS

The data from this protocol and that of 78/29 and 78/30 were presented at the Annual Clinical Investigation Conference, San Antonio, TX Sept 1980. The principle investigator has been reassigned and no further work is anticipated in the near future at WBAMC.

STATUS: Completed



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Quantitative and Qualitative Phenolic Acid Changes in Rats  
Treated with Catecholamine Pathway Inhibitors

WORK UNIT NO: 78/29

PRINCIPAL INVESTIGATOR: MAJ M.F. Sellers, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Acid metabolites of L-DOPA, i.e., homovanillic acid (HVA), dihydroxyphenylacetic acid (DOPAC), Vanilmandelic acid (VMA), p-hydroxyphenylacetic acid, m-hydroxyphenylacetic acid, and p-hydroxymandelic acid will be qualitatively measured in urine of rats pretreated with monoamine oxidase inhibitors, and B-hydroxylase inhibitors, then treated with radioactive ( $^{14}\text{C}$ ) L-DOPA. The purpose of this study is to determine the effect of catecholamine pathway inhibitors on end metabolism acids.

TECHNICAL APPROACH

Weanling rats will be divided into test and control groups. Test animals will be subjected to various regimens of catecholamine pathway inhibitors such as B-hydroxylase, monoamineoxidase, and decarboxylase inhibitors. Endogenous catecholamine metabolite acids will be measured in urine and compared to control animals. Exogenously administered radioactively ( $^{14}\text{C}$ ) labeled L-DOPA will be given to both test and control animals and again acid metabolites will be measured in rats urine and compared to control animals. Urinary catecholamine acids will be measured by current techniques including gas chromatography, thin layer chromatography, etc. Scintillation counts will be performed on each acid fraction. Determinations and conclusions will be made from comparing endogenous and exogenously labeled metabolites by paying careful attention to changes in specific activity and quantitation changes after exogenous L-DOPA injections. Catecholamines may also have to be determined in order to study feedback inhibition and metabolic pathway shunt studies.

CONSUMABLE SUPPLIES

\$206

PROGRESS

The data from this protocol was presented at the Annual Clinical Investigation Conference, San Antonio, TX, Sep 1980. The principal investigator has been reassigned and no further work is anticipated in the near future at WBAMC.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Minor Amino Metabolites of L-DOPA

WORK UNIT NO: 78/30

PRINCIPAL INVESTIGATOR: MAJ M.F. Sellers, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Weanling male rats will be injected with altered L-DOPA. Metabolism will be studied in the rat model.

TECHNICAL APPROACH

Forty male weanling Sprague-Dawley rats will be divided into four groups. The ten animal control group will be fed normal rat TEKAD diet. Thirty animal test groups will have methionine supplement either by intubation or mixed with the TEKAD pellets. The animals will be kept on this diet for ten days. Test animals will be further broken down into three groups of ten animals. Animals will be sacrificed at intervals starting at 2-24 hours after L-DOPA injection. Urine will be collected during this time. Brain, liver, and urine will be extracted for N- and O-methylated amines. They will be quantitatively and qualitatively determined by GC, GCMS, TIO, LC, etc.

PROGRESS

The data from this protocol was presented at the Annual Clinical Investigation Conference, San Antonio, TX, Sep 1980. The principal investigator has been reassigned and no further work is anticipated in the near future at WBAMC.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Role of Deoxyribonucleic Acid Attachment to Cell Membrane  
in the Regulation of Bacterial Growth

WORK UNIT NO: 79/01

PRINCIPAL INVESTIGATOR: Robert Frederick, PhD, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To isolate and examine specific deoxyribonucleic acid (DNA) sequences associated with bacterial cytoplasmic membranes.

TECHNICAL APPROACH

Our initial experiments are designed to analyze the effect of different restriction enzymes on isolated nucleoids. These are the folded chromosome of the bacteria which can be isolated in their compact state while retaining the membrane association. The procedure can be done simply with reasonable yields under salt and pH conditions which will facilitate endonuclease treatments. Once isolated, the tritium labeled nucleoids (i.e. the entire chromosomes) will be digested with commercially available restriction endonucleases. These enzymes cleave the DNA molecules at specific nucleotide sequences resulting in specific fragments which can subsequently be separated by agarose gel electrophoresis and resolved on x-ray film by autoradiofluorography. Membrane associated fragments will be purified by fractionation using the magnesium-sarkosyl crystal separation technique. The fragments will be recovered by standard techniques and analyzed by agarose gel electrophoresis. Once the specific sequences have been resolved, we will begin to identify what regions of the chromosome are involved and under what conditions. The relationship of the attachment to bacterial growth may then be examined by varying the growth conditions of the organisms, using appropriate mutant strains and in the presence of various antibiotics.

CONSUMABLE SUPPLIES

\$615

PROGRESS

We have repeated earlier experiments with different restriction enzymes *Him* & *III* and *Sal* I. The results from the *Him* & *III* experiments are consistent with those initially reported for the *Eco* RI system. By estimating the average molecular weight of the membrane associated DNA restriction fragments, we have calculated approximately 25 chromosomal attachment sites. These data are very much in agreement with the

Work Unit No: 79/01

published values of 18 to 30. We are now perfecting our agarose gel analysis to allow a better estimation of the molecular weights of the larger fragments isolated and confirming our findings of preferential separation of unique membrane associated DNA fragments.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Synthesis of Inhibitors of the Shikimate Pathway for Investigation  
TITLE: As Potential Antimicrobial Agents

WORK UNIT NO: 79/07

PRINCIPAL INVESTIGATOR: David Rauls, PhD, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The 6-alpha and 6-beta fluoro analogs of shikimic acid will be synthesized as potential irreversible inhibitors of the pathway responsible for aromatic acid synthesis in microorganisms. The compounds will then be evaluated for antibacterial activity using a standard antibacterial screen.

TECHNICAL APPROACH

The desired 6-fluoro analogs of shikimic acid will be synthesized by established synthetic techniques. The antimicrobial activity will be determined using standard assays. The anticipated limiting factors appear to be related to the potential lability of the products.

PROGRESS

After synthesizing the protected derivatives of shikimic acid, further reaction with n-bromosuccinimide to produce the 6-bromo compound was attempted. Due to steric hindrance, the desired bromination did not occur. Gas chromatography-mass spectrometry of the reaction mixture indicated recovery of starting material and will be required to devise another synthetic approach to the desired product.

TABLE: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Maternal Serum and Urinary Steroid Concentrations During  
TITLE: Contraction Stress Testing

WORK UNIT NO: 8005

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if any changes occur in maternal serum steroid concentrations during contraction stress testing, and if so, are they of predictive value in regard to fetal outcome.

TECHNICAL APPROACH

All patients admitted for contraction stress testing will be asked to participate. A two-hour urine specimen prior to beginning and another immediately from starting the oxytocin will be collected. Three to five cc of venous blood will be drawn from the arm opposite the IV infusion at 0, 30, 60 and 120 minutes of the test. The blood will be drawn in three 1 cc aliquots from the same venipuncture at five minute intervals around each drawing time and the serum combined in equal volume to compensate for variabilities in serum estradiol. Specimens will be analyzed for estradiol and total estradiol and an aliquot frozen for possible analysis of cortisol, progesterone and other steroids which are considered as indicators of fetal well being. All specimens from positive, equivocal, or, in retrospect, false negative tests, will be analyzed following randomization assignment. Twenty negative studies will be used to compare mean urinary and serum levels at each time period from control and study group patients. Any significant differences will be correlated in an attempt to define equivocal, false positive and negative test results.

REFERENCES

1. Penney, L.L. et al. J. Clin. Endocrinol. 40: 1080, 1975.

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Comparison of Patient's Satisfaction with Patient's and  
TITLE: Nurse's Perception of Pain

WORK UNIT NO: 80/14

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MC

ASSOCIATE INVESTIGATORS: Ann Bechtel, RN

OBJECTIVES

To gather data which may be helpful to increase nurse's effectiveness in providing pain relief.

TECHNICAL APPROACH

Data will be collected via structured interviews in the form of questionnaires and review of records for demographic data, which will be analyzed through the use of statistical methods. The sample will consist of approximately 25 patient-nurse situations. The patient experiencing pain and the nurse responding to this patient in pain will be considered a patient-nurse situation. All subjects will be English-speaking, military or civilian, males or females, eighteen years of age and older. The patient subjects will be those persons expressing discomfort/pain at least 12 hours after elective surgical procedures. The nurse subjects will be those registered nurses responding and attending to the patient subjects.

PROGRESS

Twenty-five patients and thirteen nurses participated in this study. The results supported the protocol hypothesis. A dissertation for the Master of Science degree in Nursing originated from this project. Ann Bechtel successfully defended the thesis to complete her degree requirements.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Holographic Analysis of Stress Produced in a Pier Abutment  
Fixed Partial Denture

WORK UNIT NO: 72/08

PRINCIPAL INVESTIGATOR: LTC R.T. Brown, DC

ASSOCIATE INVESTIGATORS: MAJ T.S. Strain, MAJ R.R. Larson

OBJECTIVES

To demonstrate the distribution of stress in rigid and non-rigid pier fixed partial dentures with the use of holographic birefringence. To demonstrate the usefulness of the hologram as a stress measuring instrument in prosthetic dentistry and to unequivocally prove the need for nonrigid connectors in pier abutment fixed partial dentures.

TECHNICAL APPROACH

Outline of phases of investigation: A five-unit pier fixed partial denture will be fabricated using rigid connectors. A holograph will be made of the FPD in an unstressed mode. The FPD will be stressed with forces from 1-21 lbs in increments of 2 lbs. The point stress will be placed over each abutment individually, as in an ideal occlusion, with the points in central fossas and with a bolus of food. Holograms of the model in the stressed mode will be superimposed over the unstressed mode and the birefringence will be recorded on film. The same procedure will be carried out using a five-unit pier fixed partial denture fabricated using a nonrigid connector.

PROGRESS

Differences found between stressed and unstressed modes were inconsistent. The results were not conclusive. No further work is contemplated.

STATUS: Terminated



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Antibiotic Prophylaxis in Intraoral Orthognathic Surgery

WORK UNIT NO: 79/09

PRINCIPAL INVESTIGATOR: MAJ J.E. Ruggles, DC

ASSOCIATE INVESTIGATORS: COL J.R. Hann, DC

OBJECTIVES

To conduct a prospective double-blind comparison of two prophylactic antibiotic regimens in patients undergoing intraoral orthognathic surgery of the maxilla and/or mandible.

TECHNICAL APPROACH

Drugs to be administered in the study are Procaine Penicillin G and Aqueous Penicillin G.

a. Aqueous Penicillin G is the antibiotic agent of choice for almost all infections originating in the oral cavity, and consequently almost all infections resulting from intraoral orthognathic surgery.

b. Some controversy exists concerning what constitutes an appropriate period for prophylaxis.

(1) Peterson and Booth, in a retrospective study of patients undergoing intraoral orthognathic surgery, reported an 11.4% incidence of postoperative infection in patients who received prophylactic antibiotics, and an 11.1% incidence of postoperative patients who received no antibiotics.

(2) In a retrospective study by Yrastorza, the incidence of postoperative infection in patients undergoing intraoral orthognathic surgery was smaller in patients receiving no prophylactic antibiotics than for patients who received antibiotics for an average of eight days postoperatively.

(3) Zallen and Black presented what they termed current thoughts regarding the use of prophylactic antibiotics in orthognathic surgery. They recommended the use of antibiotics, but gave no recommendations concerning duration of coverage, and presented no statistical information to support their views.

4. The presented guidelines for prophylactic antibiotic coverage in surgery, in fact, have advocated use of antibiotics only during the immediate postoperative period. However, no statistics were presented.

(5) To our knowledge, a prospective, double-blind study comparing short term and longer term prophylactic antibiotic coverage for intraoral orthognathic surgery has not been reported.

Patients eligible for inclusion in the study must be adults eighteen years of age and older, may be of either sex, and may be civilian or military.

Patients will be excluded from the study if they give a history of allergic reaction to penicillin or other Beta Lactam antibiotic, if they have a compromised immune defense system, or if they have received antibiotic therapy within the previous fourteen days.

Total numbers of patients will be forty, divided into two groups of twenty patients.

#### Antibiotic Regimens:

(1) All patients will receive

- 600,000 units Procaine Penicillin G and 400,000 units Aqueous Penicillin G, I.M., one hour preoperatively.
- 2,000,000 units Aqueous Penicillin G, I.V. over 30 minutes every three hours intraoperatively.
- 2,000,000 units Aqueous Penicillin G, I.V. over 30 minutes three hours after the last intraoperative dose.

(2) Group I (20 patients) will receive

- 2,000,000 units Aqueous Penicillin G, I.V. over 30 minutes every four hours for a total of twelve doses.

(3) Group II (20 patients) will receive

- A placebo I.V. over 30 minutes, every four hours for a total of twelve doses.

Method of Followup: Followup will consist of routine postoperative care, to include observation for signs of postoperative infection. The diagnosis of postoperative infection will be made if three of the following criteria are met:

(1) Elevation of body temperature for longer than 72 hours post-operatively.

(2) Increased edema, induration, and erythema of wound margins and surrounding tissue.

(3) Drainage of purulent exudate from the wound.

(4) Positive serial blood cultures.

Postoperative infections, once diagnosed, will be treated with local measures and the appropriate antibiotic(s) based upon culture and sensitivity results.

All infections will be cultured utilizing both aerobic and anaerobic methods.

#### PROGRESS

Patient entry is complete. Data analysis is in progress.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BLAUMONT ARMY MEDICAL CENTER  
Ft. PASO, TEXAS 79920

DETAIL SHEET

TITLE: Serum Glucose Level In Relation to Recovery Time from General Anesthesia for Outpatient Oral Surgery Procedures.

WORK UNIT NO: 80/29

PRINCIPAL INVESTIGATOR: MAJ D.B. Boyd, DC

ASSOCIATE INVESTIGATORS: MAJ G.D. Jeffrey, DC

OBJECTIVES

To conduct a study to determine if there is a direct relationship between a patient's serum glucose level and the length of time required to sufficiently recover from a halothane general anesthetic.

TECHNICAL APPROACH

An attempt to detect a relationship between serum glucose level and recovery time from patients undergoing general anesthesia will be studied. Patients eligible for inclusion in the study must be eighteen years of age or older, may be of either sex, nonpregnant, and may be dependents of military personnel or active duty military personnel. Patients must require minor oral surgery procedures which can be accomplished in forty (40) minutes or less on an outpatient basis. All patients will be NPO at least eight hours. All patients will receive general anesthesia. Blood samples for serum glucose determination will be obtained from all patients at 1-5 minutes preinduction; 1-5 minutes following discontinuation of the halothane; 1-5 minutes following sufficient recovery. Intravenous fluid will be 1/2 NS via standard infusion apparatus in one half the group, and 1/2 NS/5%D in the remaining one-half. Determination of recovery time : Time shall begin upon discontinuation of the halothane; time shall run until sufficient recovery has taken place to allow release; A score of 9 or 10 on a modified postanesthesia recovery score (PARS) as proposed by Arlow shall be sufficient recovery.

PROGRESS

Control patients and half of the study patients have been entered. We expect completion of the clinical portion by mid-February.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Effect of a Broad Spectrum Antibiotic on the Course of Viral URI

WORK UNIT NO: 76/23

PRINCIPAL INVESTIGATOR: LTC R.E. Morrison, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine in a controlled double-blind study the effect of an antibiotic on the clinical course of acute viral upper respiratory tract infections with particular attention to any beneficial or deleterious effects of the treatment with respect to secondary bacterial complications.

TECHNICAL APPROACH

Patients admitted to the Acute Respiratory Distress (ARD) ward without obvious bacterial infections will be divided into two random groups. One group will receive tetracycline HCl, the other a placebo. The physician taking care of the patients, and the patients themselves, would not know whether they were receiving drug or placebo. The code would be held by the Pharmacy Service. The incidence of complications, in particular, secondary bacterial infections; the total length of fever; the general well-being; length of hospital stay; incidence of adverse drug reaction; and the total cost of treatment would be compared between the two groups.

PROGRESS

Staffing shortages have also caused suspension of this study. Another attempt to institute it with the next URI season is anticipated.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Diagnostic Adrenal Scanning with  $^{131}\text{I}$  (NP59)

WORK UNIT NO: 76/33

PRINCIPAL INVESTIGATOR: LTC T. Brown, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this study is to determine the usefulness of  $^{131}\text{I}$ -NP59 in scanning of the adrenal glands. It will be employed for the following purposes: (a) as a screening test for detection of primary aldosterone tumor, Cushing's disease, adrenal cortical adenoma, or pheochromocytoma, (b) imaging of adrenals in patients who require adrenal venography and are allergic to contrast media, (c) detection of unilateral adrenocortical hypofunction: calcification, metastatic carcinoma, post-venography infarction, etc., (d) detection of functioning adrenal remnant after adrenalectomy for Cushing's syndrome, (e) aid in assessment of adrenocortical steroid therapy.

TECHNICAL APPROACH

Patients with clinical evidence of adrenal disease will be studied upon referral from the Endocrine Service. Adrenal imaging will be performed after injection of the material to assess the presence or absence of visualization of the adrenal glands, their size and response to suppression therapy.

PROGRESS

NP59 appears to be a satisfactory agent for adrenal imaging. No patients were entered in FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BLAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Comparison of Cellular Metabolic Indices with Thyroid Dysfunction  
TITLE: and Therapy

WORK UNIT NO.: 78/

PRINCIPAL INVESTIGATOR: LTC M.J. Sellers, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To clarify the relationship and clinical usefulness of systolic time intervals as an index of cardiac output and myocardial contractility,  $O_2$  consumption at rest and at steady state exercise, 2,3-diphosphoglycerate (2,3-DPG), measurements in hyperthyroid, euthyroid and hypothyroid patients and to evaluate the possible use of these parameters in monitoring therapeutic interventions.

TECHNICAL APPROACH

Prior to initiation of therapy, hypothyroid and hyperthyroid patients will be screened for factors influencing 2,3-DPG levels. The patients will then undergo testing of hematocrit, hemoglobin, 2,3-DPG,  $pO_2$ ,  $pCO_2$ , pH, bicarbonate, serum  $CO_2$ ,  $O_2$  consumption at rest and exercise steady state, and systolic time intervals at rest. Hyperthyroid patients will be tested prior to therapy, after one week of propranolol therapy and at time of achieving a clinical and thyroid function euthyroid state by means of  $^{131}I$  therapy and/or propylthiouracil or methimazole. Hypothyroid patients will be tested prior to therapy and at time of achieving a clinical and thyroid function euthyroid state by means of levothyroxine therapy. Euthyroid goiter/nodule patients will be tested prior to therapy and at a therapeutic steady state approximately two months after initiation of suppression therapy with levothyroxine. Factor analysis will be applied to clinical indices, thyroid function tests, 2,3-DPG, systolic time intervals and resting and exercise steady state  $O_2$  consumption with correlations being made to thyroid dysfunction state and therapeutic measures utilized.

PROGRESS

The original principal investigator has resigned, and LTC Sellers of the Dept of Clinical Investigation is managing the data. The DCI is attempting to interest newly assigned staff in completing this protocol.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Minoxidil as an Anti-hypertensive in Patients Refractory to  
TITLE: Available Medications

WORK UNIT NO: 78/13

PRINCIPAL INVESTIGATOR: CPT L.M. Lehmer, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The objective of this protocol is to test the hypothesis that Minoxidil is an effective alternative treatment for patients whose blood pressure is refractory to available drugs or who have experienced unacceptable side effects from them and whose situation is life-threatening. Another purpose is to document clinical experience with minoxidil in a manner that will provide a basis for extrapolation of the results to the specified hypertensive population.

TECHNICAL APPROACH

Patients with severe hypertension, unresponsive to conventional medication and in a life threatening situation will be placed on a regimen of Minoxidil. The ultimate purpose is to control refractory blood pressure problems such as sustained severe, accelerating, or malignant hypertension. Very thorough recordkeeping will be maintained documenting unresponsiveness to conventional treatment and responsiveness to Minoxidil.

PROGRESS

Minoxidil is now an FDA approved medication. A final annual review was conducted by the WBAMC Institutional Review Committee and forwarded as per regulation, to OTSG and the FDA. Three patients were treated.

STATUS: Terminated



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Separation and Identification of CPE Isoenzymes by  
TITLE: Radioimmunoassay Technique

WORK UNIT NO: 78/31

PRINCIPAL INVESTIGATOR: LTC H.W. Henry, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this study is to develop a routine method for measuring CPK isoenzyme levels with emphasis on the MB fraction using RIA techniques.

TECHNICAL APPROACH

Individual isoenzymes of CPK obtained from commercial sources will be injected into rabbits to elicit specific antibody responses. The analysis for CPK would be performed by classical RIA techniques. CPE would be tagged and reacted in varying concentrations with the individual antibodies produced and harvested from the rabbits. Standard concentration curves and cross-reactivities would be established to determine RIA specificity. From the standard curves, unknown CPK concentrations in serum will be determined. It would then be possible to correlate values for the MB fraction in the normal and infarcted populations.

CONSUMABLE SUPPLIES

\$240

PROGRESS

None

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Techne-99m-pyridoxylidoneglutarate (Tc-99m-PG) for  
TITLE: Diagnosis of Hepatobiliary Disease

WORK UNIT NO: 79/05

PRINCIPAL INVESTIGATOR: LTC H.W. Henry, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the clinical efficacy of Tc-99m-PG as a diagnostic hepatobiliary and gallbladder agent. Tc-99m-PG is presently being evaluated for its ability to provide clinically useful information regarding biliary tract and gallbladder disease processes. This radionuclide has already been shown to be valuable in the assessment of hepatobiliary function, diagnosis of acute cholecystitis, evaluation of gallbladder dysfunction, and in differentiation of hepatocellular disease from extrahepatic obstructive jaundice.

This additional diagnostic agent could provide more rapid diagnoses in diseases of the biliary tract and gallbladder than with the standard methods presently available. Earlier diagnoses of abnormalities could decrease patient suffering overall and particularly in the acutely ill.

Tc-99m-PG has been demonstrated to have a wide margin of safety, thereby avoiding the risk of reactions. A high incidence of reactions, including fatal reactions, is known to occur with intravenous cholangiographic contrast materials utilized in conventional radiography. The actual incidence of reactions to intravenously administered cholangiographic contrast media overall is not accurately established since no consistent efforts have been made to report nonfatal reactions. The incidence of fatal reaction following intravenous cholangiography is approximately 0.0025% or 1:40,000. Because of the rapid blood clearance of Tc-99m-PG more rapid diagnoses may be made in acute cholecystitis (i.e., within one hour), whereas, conventional radiographic methods may require several hours. Quantitative assessment of hepatobiliary function is possible with Tc-99m-PG. Tc-99m-PG may allow improvised visualization of the biliary system, even when the serum bilirubin level is mildly elevated.

lack of radiation dose to the gallbladder. The gallbladder will be studied with 1-131 sodium iodide.

#### Study Population

The patient population for this study will include patients with suspected or confirmed gallbladder disease, acute or chronic hepatitis, or chronic cholecystitis.

Patients who are pregnant, lactating, or under 18 years of age will not be included in the study. Patients who are unable to benefit to be gained out of the study will not be included. Patients of childbearing age will be advised to avoid pregnancy following the onset of menarche. Patients will be evaluated for benefit or harm. The criteria for patients will be the above criteria will be included intravenously with 1-131. The adult dose will consist of approximately 1 mCi. For patients under 18 years of age that dose will be calculated according to the weight or body surface area of the patient. Each patient study will be carried out under the supervision of a physician. The instruments used for detection will be the gamma scintillation cameras located at the William Beaumont Army Medical Center, Nuclear Medicine Service.

Each patient will be studied following a 1-6 hour period of fasting when possible. Following intravenous administration of the Tc-99m PIP sequential scintiphotos will be obtained at 5 minute intervals for up to one hour following injection. Simultaneous computer acquisition of the data will be obtained for further analysis. Nuclear images will be made and stored on film and/or on magnetic tape or data storage disks. Curve plot data can be subsequently derived from this information when appropriate.

In selected patients who have suspected chronic gallbladder disease, delayed images may be obtained at 2-4 hours post-injection when deemed necessary. If gallbladder dysfunction is suspected in patients who have chronic symptoms but who have been shown not to have calculi by routine oral cholecystography evaluation of gallbladder emptying may be obtained by intravenous injection of Kinevac (Sincalide for injection, manufactured by E.R. Squibb & Son, Inc. and currently used in routine oral cholecystography). The dose recommended by the manufacturer is 0.02 mcg. per kg. This methodology offers the advantage of a standardized, precise and reproducible quantitative assessment of gallbladder contractility (better than oral fatty meals etc., used in conventional radiographic techniques in the past). This will allow computer analysis and printout of data for determination of a washout curve as gallbladder emptying occurs. Prescription forms, patient charts, and consultation forms will be used to record pertinent data.

## DISCUSSION

To date, 25 patients have been studied with isradipine. Laboratory and the studies have been highly useful in making clinical decisions, particularly in patients with suspected acute cholecystitis. At the current time, this noninvasive mode of examination is the best and replaced the intravenous cholangiogram in evaluation of patients with suspected acute cholecystitis, thereby decreasing the risk of adverse reactions. The project is under continuation to evaluate means of high quality imaging of the biliary tract.

## TABLE I. Summary

[illegible]

1. *Journal of the American Medical Association*, 1997; 277: 1039-1043.

1. *Journal of the American Medical Association*, 1997; 277: 1033-1038.

1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 2675, 2676, 2677, 2678, 2679, 26

[illegible]

Work Unit 72/13

the study to have meaningful results. It should take from nine months to one year to accumulate the patients and laboratory data. Controls will consist of people with acute insufficiency with definite etiology.

#### PROGRESS

The original principal investigator has been reassigned. He studied no patients. LTC Mansfield has assumed this protocol.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Clearing of Bacteria from Sputum of Patients with Chronic  
Bronchitis or Pneumonia Following Antibiotic Therapy

WORK UNIT NO: 79/14

PRINCIPAL INVESTIGATOR: CPT H.M. Richey, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The objective of this study is to determine the amount of time required for sputum from patients with chronic bronchitis and/or pneumonia to become clear after antibiotic therapy is initiated.

TECHNICAL APPROACH

The rate of clearing of bacteria from urine and blood following antibiotic therapy has been described. In respiratory disease the rate of clearing of clinical symptoms and radiographic abnormalities is known. However, the rate of clearing of bacteria from sputum in patients with infected airways or pneumonia is not known. The purpose of this study is to determine that rate of clearing. Correlation with clinical status and response to therapy will be analyzed.

Patients admitted to the medical services of William Beaumont Army Medical Center with chronic bronchitis or pneumonia will have a sputum collected for gram stain and culture on admission. After appropriate antibiotics have been begun, subsequent sputum samples will be collected for gram stain at 6, 12, 24 and 48 hours after admission and the presence or absence and type of bacteria present will be noted.

Patients admitted with the above diagnoses will be used regardless of age and sex. Thirty to fifty patients will be used. No controls will be included. The approximate time to completion will be about six months.

PROGRESS

The principal investigator was reassigned. This study will be initiated by the new principal investigator, CPT Richey.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7410: Chronic Lymphocyte Leukemia Protocol

WORK UNIT NO: 79/15

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the response rate, both complete and partial, in chronic lymphocytic leukemia, to combination chemotherapy with: (a) Cyclophosphamide, adriamycin and prednisone (CAP) as primary therapy in patients who have had no prior chemotherapy. (b) CAP as secondary therapy for those patients who have previously received low dose chlorambucil. To assess the effectiveness of intermittent cyclophosphamide and prednisone in maintaining a remission.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigations Department, WBAVC and are available upon request.

PROGRESS

This study phase has been closed by SWOG. No patients were entered at WBAVC.

STATUS: Terminated



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7433: Stage I & II Non-Hodgkins Lymphoma

WORK UNIT NO: 79/16

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the remission rate, remission duration and survival in patients with non-Hodgkin's lymphoma, pathologic stages I, II, III<sub>E</sub> treated with extended field radiotherapy (supradiaphragmatic mantle or abdominal field) alone, with extended field radiotherapy plus combination chemotherapy.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department WBAMC, and are available upon request.

PROGRESS

No patients were entered in FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7436: Combined Modality Therapy of Breast Cancer

WORK UNIT NO: 79/17

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the effect of two adjuvant chemotherapy programs upon the time to recurrence and upon the percentage of recurrence in post-operative breast carcinoma patients who have a high risk of developing metastases. To compare the effect of these adjuvant chemotherapy programs upon the survival pattern of such patients.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBANC, and are available upon request.

PROGRESS

One patient was entered and is well. This study phase has been closed by SWOG.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE:SWOG 7440: Adjuvant Chemotherapy for Osteogenic Carcinoma

WORK UNIT NO: 79/18

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the efficacy of combination chemotherapy with CY-VA-DIC (cyclophosphamide, vincristine, adriamycin and DIC) in preventing the development of metastases in patients with osteogenic sarcoma who have received definitive surgery for their primary lesions and who have no evidence of residual disease. To determine the survival and disease-free interval pattern of patients on this study to be compared with historic controls in the medical literature.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

This study phase has been closed by SWOG. No patients were entered at WBAMC.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7510: Adjuvant Chemotherapy for Patients with  
TITLE: Locally Advanced Adenocarcinoma of the Large Bowel

WORK UNIT NO: 79/19

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the efficacy of adjuvant chemotherapy with the highly effective combination of Methyl CCNU (MeDINU) and 5-Fluorouracil (5-FU) and to determine whether this is added to by immunotherapy with oral Bacillus Calmette-Guerin (BCG) on the disease-free interval and survival of patients with Duke C large bowel adenocarcinoma.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

Three patients were entered and one expired. This study phase has been closed by SWOG.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7518: Stage IIIA and B Hodgkins Disease Remission Induction  
TITLE: by Radiation Therapy Plus Chemotherapy Combination Versus Chemo-  
therapy Alone.

WORK UNIT NO: 79/20

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the effectiveness of 10 courses of a 5-drug combination chemotherapy (including nitrogen mustard, vincristine, procarbazine, prednisone, and bleomycin) program against the combined 3 courses of chemotherapy followed by total nodal irradiation therapy program for complete remission induction in patients with Stage III asymptomatic or symptomatic-B Hodgkin's Disease.

To evaluate the systematic "restaging" of patients in apparent complete remission.

To assess the length of unmaintained remission after intensive induction with 10 courses of chemotherapy treatment versus the combination chemo-radiation therapy, after documentation of CR status by careful "restaging."

To assess the toxicity of the chemotherapy alone portion of the study versus the toxicity of the combination of chemotherapy and radiation therapy.

To intercompare the results of this program with those to be obtained by the ongoing MOPP #5 study (SWOG-7406).

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

One patient was entered and is well. This study phase has been closed by SWOG.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7521: Adjuvant Melanoma

WORK UNIT NO: 79/21

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the efficacy of BCNU, hydroxyurea, and imidazol carboxamide (BHD) in preventing the recurrence of disease and prolonging the survival of patients with primary malignant melanoma who have received definitive surgical treatment for their primary lesions, have no evidence of residual disease but in whom by the clinical and pathological characteristics of the primary lesion can be predicted to have a high incidence of recurrence.

To determine the efficacy of combination chemotherapy (BHD) with and without BCG in preventing the development of metastases and prolonging the disease-free interval and survival of patients with recurrent malignant melanoma which has been surgically excised ("Minimal residual disease").

To determine the immunocompetence of patients with malignant melanoma and any correlation with prognosis.

To determine the influence of chemotherapy and chemioimmunotherapy upon the immunocompetence of these patients with malignant melanoma.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAAC, and are available upon request.

PROGRESS

No patients were entered in FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7613 Combination Chemotherapy for Advanced Soft Tissue Sarcomas

WORK UNIT NO: 79/22

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the maximal effective chemotherapy induction regimen for patients with disseminated soft tissue sarcomas who have probability of response >50%. To determine if cycling the use of adriamycin and maintenance with CY-DIC-DAC increases the duration of CR's treated initially with A-DIC.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department., WBAMC, and are available upon request.

PROGRESS

This study phase has been closed by SWOG. No patients were entered at WBAMC.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7630: (Chemotherapy of Advanced Prostatic Cancer

WORK UNIT NO: 79/23

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the rate or response of hydroxyurea to a two-drug combination of adriamycin and cyclophosphamide in patients with advanced carcinoma of the prostate who have measureable disease (Stage D-bone metastases or extrapelvic disease).

To compare the duration of survival in patients with no measureable disease treated with one of the treatment regimens.

To estimate the response rate to each crossover regimen in patients that have been treated and did not respond to one of the regimens.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

This study phase has been closed by SWOG. No patients were entered at WBAMC.

STATUS: Terminated



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE:SWOG 7632: Combined Modality for Recurrent Breast Cancer

WORK UNIT NO: 79/24

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Establish the survival of breast cancer patients when treating the first recurrence with a coordinated hormonal chemotherapeutic approach.

Determine the efficacy of a response to the antiestrogen Tamoxifen in predicting response to ablative surgery.

Correlate hormonal manipulations with estrogen and progesterone receptors where possible.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

No patients were entered in FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE SWOG 7635: Combined Modality for Limited Squamous Carcinoma of Lung

WORK UNIT NO: 79/25

PRINCIPAL INVESTIGATOR: R.A. P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine whether chemotherapy with adriamycin and/or immunotherapy with levamisole, improve median survival of split-course radiotherapy used alone in the treatment of patients with limited extent, squamous bronchogenic carcinoma.

To determine the qualitative and quantitative toxicity of each treatment regimen.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAHC, and are available upon request.

PROGRESS

Two patients were entered and both expired. This study phase has been closed by SWOG.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
CHILDS MEMORIAL HOSPITAL MEDICAL CENTER  
JANUARY 1, 1980, FAX 799-26

CLINICAL TRIAL

RESEARCH PROJECT: Treatment of Glioma with BCNU, MFC, and  
radiation therapy plus MFC, and MFC, and radiation therapy  
plus Precarbazine for remission induction, duration of remission, and  
survival in patients with malignant gliomas of the brain.

PRINCIPAL INVESTIGATOR: M.D. J. Harlow, M.D.

ASSOCIATE INVESTIGATOR:

OBJECTIVES

The purpose of this study is to compare the effectiveness of radiation  
therapy plus BCNU, radiation therapy plus MFC, and radiation therapy  
plus Precarbazine for remission induction, duration of remission, and  
survival in patients with malignant gliomas of the brain.

TECHNICAL APPROACH

The details are lengthy and specified in the original SB000 protocol.  
Duplicates are kept on file in the Clinical Investigation Department,  
SBMC, and are available upon request.

PROGRESS

No patients were entered in FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BLAUNDT ARMY MEDICAL CENTER  
11 FASO, TEXAS 79920

DETAIL SHEET

AC 72475: Chemotherapy for Multiple Myeloma: VMCP +  
VCAP vs VMCP + VBAP for Induction Therapy: VMCP vs VMCP +  
Levamisole for Maintenance  
OP 111 N1: 79/27

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the effectiveness of three intermittent pulse chemotherapy combinations VMCP + VCAP vs VMCP + VBAP vs MP for induction of remissions in previously untreated patients with multiple myeloma. Results will also be compared with other combination chemotherapy treatments in previous SWOG studies, especially VMCP treatment in 72474 and previous studies of MP combinations.

For patients proven to have at least a 75% tumor regression after induction, to compare the value of 12 months of chemimmunotherapy maintenance VMCP + levamisole in comparison to VMCP alone.

Establish baseline and serial data on immunologic status in these patient groups.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAAC, and are available upon request.

PROGRESS

One patient was entered and expired.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
FEDERAL BUREAU OF ARMY MEDICAL CENTER  
Ft. DAVIS, TEXAS 79720

DETAIL SHEET

SWOG 7713: Chemotherapy in Non-Hodgkins Lymphoma (CHOP vs  
TITLE: CHOP + Levamisole vs CHOP + Levamisole + BCG for Remission  
Induction Therapy

WORK UNIT NO:

79/28

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the effectiveness, in terms of rate of response to chem-  
immunotherapy regimens (CHOP + Levamisole vs CHOP + Levamisole + BCG  
against CHOP for remission induction in previous untreated patients  
with non-Hodgkin's lymphoma

For patients proven to be in complete remission after induction, to  
compare the duration of documented complete response obtained by  
continued maintenance immunotherapy with Levamisole vs no maintenance  
therapy.

For patients with impaired cardiac function (not eligible for treatment  
with Adriamycin), with mycosis fungoides, or with only a partial response  
to 11 courses of treatment with CHOP-Levamisole-BCG, to estimate the  
complete response obtained by continued chemimmunotherapy with CHOP +  
Levamisole.

To estimate the CNS relapse rate in patients with diffuse lymphomas  
when CNS prophylaxis with intrathecal cytosine arabinoside is used.

To continue to evaluate the impact of systematic restaging of  
patients judged to be in complete remission and the value of  
expert hematopathology review of diagnostic material from all cases.

To establish baseline and serial data on immunologic statute in both  
chemimmunotherapy groups.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol.  
Duplicates are kept on file in the Clinical Investigation Department,  
FAMC, and are available upon request.

PROGRESS

No patients were entered in 1980.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7717: Diagnostic Studies for Patients with Adenocarcinoma  
TITLE: of Unknown Origin

WORK UNIT NO: 79/29

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the yield of various diagnostic procedures in finding the site of tumor origin in patients who present with metastatic adenocarcinoma with no obvious primary source.

To compare the efficiency of combination chemotherapy using Fluorouracil, Adriamycin and Cytosin vs. Fluorouracil alone the palliative management of patients with metastatic adenocarcinoma of unknown origin.

To assess the hematologic toxicity of the chemotherapy regimen on treated patients.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAAC, and are available upon request.

PROGRESS

This study phase has been closed by SWOG. No patients were entered at WBAAC.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7725: Continuous 5-Drug Induction with Intermittent  
TITLE: CMF vs CMF + Levamisole for Maintenance in Patients with  
Estrogen Receptor Negative Breast Cancer

WORK UNIT NO: 79/30

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the respective effects of Levamisole on the duration of response and survival of patients with advanced breast cancer - currently treated with maintenance chemotherapy after a successful remission induction trial of continuous Cooper regimen.

To accumulate data on immunologic variables under the conditions of chemotherapy alone and combined chemotherapy and immunotherapy with Levamisole of advanced breast cancer.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

This study phase has been closed by SWOG. No patients were entered at WBAMC.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7727/28: Skin Test Procedures for SWOG 7727/7728

TITLE:

WORK UNIT NO: 79/31

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine remission induction rates, remission duration, survival and toxicity in patients with disseminated malignant melanoma treated with BCNU, hydroxyurea and DTIC(BHD), plus Levamisole, and intermittent single high dose DTIC plus Actinomycin D in a prospective, randomized clinical study.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, W.B.M.C. and are available upon request.

PROGRESS

Two patients were skin tested. This study has been closed by SWOG.

STATUS: Completed



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7738: Combination Chemotherapy of Pancreatic Adenocarcinoma  
TITLE: with Mitomycin C, 5-FU, and Streptozotocin, Phase III

WORK UNIT NO: 79/32

PRINCIPAL INVESTIGATOR: LTC P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the response of pancreatic adenocarcinoma to either 5-fluorouracil and mitomycin C with or without streptozotocin.'

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

This study was dropped by the Southwest Oncology Group. No patients were entered from this institution.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7802: Adjuvant Therapy of Soft Tissue Sarcoma with  
TITLE: Radiation Therapy and Chemotherapy

WORK UNIT NO: 79/33

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine whether combination chemotherapy with A-DIC can improve the results in terms of disease-free survival produced by adjuvant radiotherapy in patients with soft tissue sarcomas Stage IIB and III at high risk for recurrent disease.

To determine any difference in toxicity between patients receiving boost radiation therapy to the scar with Cobalt 60 or electron beam.

To determine any difference in local recurrence rate or disease-free survival between patients with adequate surgery and those without adequate surgery.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

This study has been closed by SWOG. No patients were entered at WBAMC.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOC 7804: Adjuvant Chemotherapy with 5-FU, Adrenarycin and  
Metorycin C (FAM) vs Surgery Alone for Patients with Locally  
TITLE: Advanced Gastric Adenocarcinoma Phase III

WORK UNIT NO:79/34

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the efficacy of adjuvant chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TMM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOC protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

No patients were entered in FY80

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE SWOG 7811: Brain Metastases Phase III

WORK UNIT NO: 79/35

PRINCIPAL INVESTIGATOR MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the effectiveness of combined radiation therapy and metronidazole (Flagyl) in the treatment of patients with brain metastases from primary malignancies outside the central nervous system, compared with radiation therapy alone, as determined by objective response (brain and/or CAT scan) and/or increase in functional neurologic level and duration of response.

To determine the toxicity of multiple dose administration of metronidazole and radiation therapy.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

No patients were entered in FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7825/24/25/26: ROAP-ADOAP in Acute Leukemia, Phase III

WORK UNIT NO: 70/56

PRINCIPAL INVESTIGATOR: M.J. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazone, vincristine, arabinosyl cytosine, and prednisone) to ADOAP (the same combination using Adriamycin in place of Rubidazone) in adult acute leukemia, as determined by remission rate, remission duration and survival.

To determine the comparative toxicity of these regimens.

To determine whether late intensification therapy at 9 months after complete remission will improve longterm, disease-free survival.

To determine whether immunotherapy using levamisole for 6 months after 12 months of complete remission on chemotherapy improves disease-free survival.

To determine reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia.

To study the effects of intensive supportive care in the management of acute leukemia.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

Two patients have been entered. One is currently undergoing study and the other expired.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7828: Combined Modality Therapy for Extensive Small-Cell  
TITLE: Carcinoma of the Lung. Phase III

WORK UNIT NO: 79/37

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To improve the complete response rate and long-term disease-free survival of patients with extensive small-cell carcinoma of the lung.

To define, qualitate and quantify the toxicity of each regimen employed.

To compare the efficacy of two non-cross resistant regimens (cell-cycle specific vs. cell-cycle-nonspecific) during induction.

To determine whether administration of a second, non-cross-resistant regimen in consolidation can convert stable disease or partial response to a better quality of response.

To determine the effect of intentional, early alternation of non-cross-resistant regimens on the complete response rate.

To determine whether "reinduction" at 24 and 52 weeks has a favorable effect on response duration and survival.

To determine whether administration of intrathecal methotrexate at "reinduction" can affect the incidence of non-brain CNS relapse.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, "BAMC", and are available upon request.

PROGRESS

Two patients have been entered. One is stable with evidence of disease and the other expired. This study has been closed by SWOG.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7835: High Dose Vincristine, Prednisone, Hydroxyuria +  
TITLE: Cytosine Arabinoside (HOAP) in the Blastic Phase of Chronic  
Granulocytic Leukemia, Phase III

WORK UNIT NO: 79/38

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the effectiveness as determined by remission rate, of the combination of high-dose vincristine, prednisone, hydroxyurea, and cytosine arabinoside (HOAP) for remission induction in patients with the blastic phase of chronic granulocytic leukemia. High-dose vincristine is used here to indicate the administration of a dose of 2 mg/M<sup>2</sup> without limiting the total dose to 2 mg.

To compare the effectiveness of this regimen in myeloid versus lymphoid blastic transformation, and in patients with poor prognostic characteristics, namely hyperdiploidy and lack of terminal deoxynucleotidyl transferase (TdT).

To evaluate the value as determined by median duration of remission and survival, of an intensive intermittent regimen of cytosine arabinoside, prednisone, and vincristine in the maintenance of remission.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, SBAMC, and are available upon request.

PI. RUSS

No patients were entered. This study has been closed by SWOG.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7903/7961: Study for Prior MOPP Failures Without Prior  
TITLE: Anthracycline

WORK UNIT NO: 79/39

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the effectiveness, as determined by response rate, of the QIOP combination of chemotherapy for remission induction in patients with advanced (Stages III or IV) Hodgkin's disease who have not had prior chemotherapy and in those with prior MOPP (no anthracyclines).

To assess the length of unmaintained remissions after intensive induction with ten courses of treatment with QIOP and after documentation of CR by restaging.

To evaluate the degree of noncross-resistance of QIOP in MOPP failures in terms of remission induction, duration of remission and survival.

To compare the toxicities and side effects of the QIOP regimen to those of MOPP.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAAC, and are available upon request.

PROGRESS

No patients were entered. This study has been closed by SWOG.

STATUS: Terminated



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7814: A Comparison of Methothexate and Cis -Platinum  
TITLE: for Patients with Advanced Squamous Cell Carcinoma of the  
Head and Neck

WORK UNIT NO: 79/40

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The objectives of this study are to determine whether cis-platinum will give a superior response rate and/or a longer remission duration than methotrexate in patients with squamous cell carcinoma of the head and neck region.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

One patient was entered and has expired. This study has been closed by SWOG.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7730: Cis-diamminedichloroplatinum in Refractory  
Disseminated Malignant Melanoma

WORK UNIT NO: 70/41

PRINCIPAL INVESTIGATOR: MAJ P.C. Farley, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the efficacy of high intermittent doses of cis-diamminedichloroplatinum (DD) (NSC-119875, CACP) in patients with advanced malignant melanoma refractory to higher priority protocols(s).

To determine the nature and extent of toxicity of this agent with the use of IV hydration only or IV hydration and mannitol diuresis.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAWC, and are available upon request.

PROGRESS

No patients were entered. The study has been closed by SWOG.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: A Comparison of Development of Sensitivity to Penicillin  
in Normal and Atopic Individuals

WORK UNIT NO: 80/1

PRINCIPAL INVESTIGATOR: LTC L.E. Mansfield, MD

ASSOCIATE INVESTIGATORS: Dr. Harold S. Nelson, Fitzsimons AMC

OBJECTIVES

To determine if people with allergic disease manufacture more IgE antibody after receiving penicillin. It would be hoped to evaluate this in the relation to normal individuals.

TECHNICAL APPROACH

Patients receiving penicillin for therapeutic reasons were tested before and after administration of oral penicillin.

PROGRESS

Data is being evaluated for formal presentation and manuscript.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Pre-Induction Screening for Reversible Bronchospastic  
Disease

APR 1971 NO: 8074

PRINCIPAL INVESTIGATOR: CPT H.M. Richey III, MS MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if pre-induction history, physical examination and pulmonary function testing can be used to identify and screen individuals with reversible airway disease. To identify those individuals with borderline pulmonary function, and prospectively correlate their pulmonary function with symptoms encountered during basic training. In those patients with borderline pulmonary function, to attempt to correlate the level of hypoxemia during exercise, as determined by an ear oximeter, with the individuals ability to perform during BCT.

TECHNICAL APPROACH

After appropriate medical explanation each BCT recruit will fill out a questionnaire regarding his family history, personal history, and past medical history regarding pulmonary diseases. While being held in the reception station, Ft Bliss each recruit will undergo pulmonary function studies to include FVC, FEV<sub>1</sub>, FEV<sub>1</sub>/FVC, FEF<sub>25-75</sub> and FEF<sub>75-85</sub>. Those individuals with subtle spirometric abnormalities (i.e. reduced mid to terminal flows) or with a positive past medical history or family history for asthma, hayfever, frequent "URI's" or dyspnea on exertion will be tested for static lung volumes, and will be given the FEV<sub>1</sub> exercise asthma protocol, with bronchodilators. Those who have undiagnosed PFT abnormalities or abnormal histories suggestive of pulmonary disease will be studied with exercising testing: patients will be exercised on a bicycle ergometer for Stage I and Stage II testing. Resting heart rate, minute ventilation, and oxygen saturation as determined by an ear oximeter will be determined. Exercise workloads will be increased by 25 watt seconds each minute. During the last 15 seconds of each one minute period, the heart rate, minute ventilation will be determined. Expired gas analysis will also be performed. The test will be continued until a heart rate of 80% of the age adjusted maximum heart rate is attained or until the patient fatigues. During exercise, each patient will be monitored electrocardiographically. All basic trainees who develop pulmonary symptoms during training will be referred to one of the investigators for evaluation and treatment. After basic training, all individuals included in the study will again be questioned regarding their pulmonary symptoms. Any individuals with new symptoms will be re-evaluated. Postrespective analysis of preinduction pulmonary functions

Work Unit No. 80/4

and preinduction symptoms will be carried out to determine if any single factor accurately predicts pulmonary symptoms during basic training.

PROGRESS

None

Status: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Evaluation of Thyroid Hormones in Alcoholic Hepatitis

WORK UNIT NO: 80/8

PRINCIPAL INVESTIGATOR: MAJ M. Anees, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The objective of this study is to delineate the physiology of thyroid hormone under the stress of alcoholic hepatitis. The intent is to determine if a defect in thyroid hormone metabolism exists and if so determine if the defect is a lack of deiodination of thyroxine (T4) or as a reversal of iodination.

TECHNICAL APPROACH

Twenty patients classified as acute alcoholic liver hepatitis will be entered into the study. Blood (10 ml) will be drawn on the day of admission for T4, T3, and rT3 studies. These studies will be repeated two more times at weekly intervals during the course of the hospital stay. Control studies will be performed on routine thyroid function study patients considered to be normal. Statistical comparison of normal versus test patient thyroid studies will be made and evaluated.

PROGRESS

This is a newly activated protocol. No results are available.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Hematologic & Metabolic Status of Sickle Cell Trait  
Individuals Following Vigorous Exercise

WORK UNIT NO: 80/10

PRINCIPAL INVESTIGATOR: LTC P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The degree of sickling, hemolysis, pH change, myolysis, and hematuria will be assessed in sickle cell trait individuals as compared to normal controls while undergoing vigorous exercise.

TECHNICAL APPROACH

Approximately 50-70 heterozygous sickle hemoglobin patients and a like number of controls will be observed. The appropriate blood and urine studies will be performed on these individuals at their place of training while engaged in the physical activity. Individuals may be asked to participate more than once in the study if they demonstrate any departures from normal. The phases of investigation will be (a) screen incoming black recruit population for sickle cell trait and other heterozygous sickle cell states. (b) On volunteer controls and subject individuals obtain baseline CBC, serum chemistry, hemoglobin electrophoresis and urinalysis during in-processing. (c) Identify subgroups of study subjects according to the level of hemoglobin S and degree of hyposthenuria: load of physical conditioning and body habitus. (d) Contrast the subgroups of study participants with each other and with a control group while they undergo the PT test of their training program with the following parameters: Changes in CBC, electrolytes, muscle enzymes, serum free hemoglobin, and % of sickling of red blood cells, urinary sediment content and assay of urine myoglobin and hemoglobin (e) Records to be kept - consent form of participants. Routine WBANC data flow sheets will be used to record results. (f) During inprocessing of recruits we hope to ask their cooperation in joining the study and will present them with a consent form describing the need to obtain blood and urine samples. Individuals who are asked to participate on more than one training occasion will be required to sign a consent for each occasion. (g) All of the above is to be coordinated with the training command.

PROGRESS

One screening session was performed in May 1980. A full scale study will hopefully be started soon.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Prospective Study of Mannitol in the Prevention of Radiographic  
TITLE: Contrast Induced Acute Renal Failure

WORK UNIT NO: 80/11

PRINCIPAL INVESTIGATOR: MAJ C.W. OLD, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The objective of this study is to perform a prospective, randomized and double-blind study of the possible protective effects of mannitol in preventing acute renal failure induced by radio contrast media.

TECHNICAL APPROACH

Approximately 20 subjects in each of two groups for each procedural category will be studied. The first procedure will be intravenous pyelography, but such procedures as coronary angiography abdominal and cranial angiography may also be studied. Patients will be ages 18 and above, active duty, dependents, and retired. The patients will be randomized blindly and either receive 500 cc of dextrose 5% water or 500 cc of dextrose 5% water plus 5% mannitol within one hour of the radiographic procedure. Additional volume supplementation will be at the discretion of the attending physician. The amount and type of contrast material used, and the type of procedure, as well as additional data, will be recorded.

Patient selection will be based upon any patient with a serum creatinine of 1.7 to 4.0 mg/L. Both inpatients and outpatients will be selected for this investigation. Patients will have an initial MAS drawn prior to radiocontrast procedure and submit routine urinalysis and spot urine for sodium and creatinine. The above studies will then be repeated 24 hours after the procedure, and 72 hours after the procedure. If a rise in the serum creatinine is noted then that particular patient will be followed on an individual basis. The group will be analyzed for differences by Student's t-test.

PROGRESS

Approximately 16 patients have been entered. The study will end with 20 patients. The clinical observations which led to this protocol have been published (Lancet 19:885, 1980).

STATUS: Ongoing



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

An Investigation into the Effects of Cromolyn Sodium on  
TITLE: Nonspecific Bronchial Hyperactivity

WORK UNIT NO: 80/16

PRINCIPAL INVESTIGATOR: LTC L.E. Mansfield, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate whether cromolyn sodium administration will cause a decrease in non-specific airway hyperreactivity. To determine if this diminution will be associated with a favorable clinical response.

TECHNICAL APPROACH

Asthmatic patients will use cromolyn by inhalation in a double-blind cross-over trial. Bronchial hyper-reactivity will be monitored by monthly histamine challenges. Twenty nonpregnant adult asthmatic patients not requiring corticosteroid therapy will be selected. They will be advised of the purpose of the study and how it will be carried out. Any subject with a history suggesting a risk of renal or hepatic dysfunction will be excluded. This study will begin in October and end in March, at which time the code will be broken. If the results suggest significant benefit for cromolyn patients, the active therapy will be offered to all patients and the study continued for six more months.

PROGRESS

Equipment for this protocol has not yet arrived, but is on order. The technical staff of the Allergy and Clinical Immunology Service is being trained in the techniques of bronchial provocation. Symptom score sheets and record materials are being assessed.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Clinical Evaluation of Renal Cortical Imaging Utilizing  $^{99m}\text{Tc}$ -  
TITLE: Kidney Scintigraph

WORK UNIT NO: 80/18

PRINCIPAL INVESTIGATOR: LTC H. Henry, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the usefulness of  $^{99m}\text{Tc}$ -Kidney Scintigraph in studying renal blood flow and renal anatomy. Intended for use in high resolution and/or tomographic imaging for evaluation of anatomic detail. Especially important for space occupying lesions and renal trauma.

TECHNICAL APPROACH

A series of adult patients who require renal radionuclide studies for diagnostic purposes will be studied in detail and compared with our standard renal agents. The imaging protocol is as follows:

1. Rapid images of the kidneys will be obtained with an Anger Scintillation Camera during the first 30 seconds following injection of  $^{99m}\text{Tc}$ -DMSA. These views will be used to evaluate the agent as a vascular flow agent.
2. Initially static images will then be obtained over the kidneys for the next 15 to 30 minutes to qualitatively evaluate early renal uptake of radionuclide and to determine its usefulness as a fast renal imaging agent.
3. Initially sequential static images will also be obtained at varying time intervals to evaluate the optimal imaging time for this agent.
4. After the results of the above steps are evaluated in the first 20 patients, a modified imaging protocol will be developed for the remainder of the study based upon the usefulness of the early static images and optimal imaging time.
5. For individual patients, the standard posterior views will be supplemented by oblique, lateral, anterior and pinhole views as required.

The patients to be studied under this protocol will meet the following criteria: (1) Nonpregnant and over the age of 18, unless special indications for study exist. (2) All will have either known or suspected alteration of renal function or anatomic morphology, i.e., no subject without manifest or suspected disease will be studied.

Work Unit 80/18

PROGRESS

Patient entry is awaiting completion of the scintillation camera room, which should occur early in calendar year 1981.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

WRAMC 7915 Prevention of Gonadal Damage in Women Treated with  
TITLE: Combination (Chemotherapy or Radiotherapy Below the Diaphragm  
for Hodgkins or nonHodgkins Lymphoma

WORK UNIT NO: 80/19

PRINCIPAL INVESTIGATOR: LTC P. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To protect the ova and follicular cells from ionizing radiation or  
chemotherapeutic damage and death by putting these cells at rest  
during active therapy.

TECHNICAL APPROACH

The details are lengthy and specified in the original WRAMC protocol.  
Duplicates are kept on file in the Clinical Investigation Department,  
WBAMC, and are available upon request.

PROGRESS

This is a newly approved WBAMC protocol. Patient entry is expected, but  
the total number is anticipated to be small.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7827 Combined Modality Therapy for Breast Carcinoma, Phase III

WORK UNIT NO: 80/20

PRINCIPAL INVESTIGATOR: LTC P. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus combination chemotherapy and oophorectomy.
2. To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone.
3. To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.
4. To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.
5. To correlate the ER status with disease-free interval and survival.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

Excellent progress is being made with patient accrual. Four patients have been entered.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7927/28 Chemotherapy for Multiple Myeloma Phase III

WORK UNIT NO: 80/21

PRINCIPAL INVESTIGATOR: LTC P. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To compare the effectiveness of four different drug combinations for remission induction in previously untreated patients with multiple myeloma. Results will also be compared with those from similar therapies in recently completed Southwest Oncology Group studies.
2. For patients with a 75% tumor reduction; to evaluate the role of 12 months of chemotherapy maintenance with VCP or VCP plus levamisole, when compared with previous experiences.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAAC, and are available upon request.

PROGRESS

Our two patients are tolerating the regimen very well.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7924 Multimodal Therapy for Limited Small Cell Carcinoma of the Lung

WORK UNIT NO: 80/22

PRINCIPAL INVESTIGATOR: LTC P. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To determine the efficacy of sequentially alternating, mutually noncross-resistant, multidrug regimens in remission induction and intensification therapy in patients with limited small cell lung carcinoma.
2. To determine the value of chest-radiotherapy added to intensive systemic chemotherapy in reducing chest recurrences, and in improvement of survival.
3. To determine the relative efficacy and toxicity of low-dose, extensive chest radiation when used in close chronologic sequence with systemic multiagent chemotherapeutic regimens.
4. To determine whether radiotherapy ports should be set according to tumor size prior to or after induction chemotherapy.
5. To determine the value of combined systemic chemotherapy and radiotherapy in the control of bulky chest disease.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

No patients were entered in FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

An Evaluation of Three Rapid Nonradioisotopic Methods for the  
TITLE: Immune Complexes in Human Disease

WORK UNIT NO: 89/23

PRINCIPAL INVESTIGATOR: LTC Lyndon E. Mansfield, MC

ASSOCIATE INVESTIGATORS: Robert Frederick, PhD, DAC

OBJECTIVES

To evaluate three different methods to detect immune complexes in human disease. It is hoped to find the one or two most useful methods through clinical research and in patient surveillance.

TECHNICAL APPROACH

Three methods will be used to measure immune complexes: laser nephelometer, an enzyme linked assay, and latex agglutination inhibition. These will be compared to C<sub>1</sub>O radioimmunoassay in their ability to detect preformed human immune complexes.

PROGRESS

Material supplies on order.

STATUS: Ongoing



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

The Development of an Enzyme Linked Assay to Measure Human  
TITLE: Allergen Specific Antibodies of the Immunoglobulins G and M  
Class

WORK UNIT NO: 80/24

PRINCIPAL INVESTIGATOR: LTC Lyndron E. Mansfield, MC - Allergy

ASSOCIATE INVESTIGATORS: Robert Frederick, PhD, DAC

OBJECTIVES

To modify the enzyme linked immunoassay developed to measure allergen specific IgE antibodies to the measurement of allergen specific IgG and IgM antibodies.

TECHNICAL APPROACH

Allergen will be chemically bound to polyethylene tubes or plastic microtiter plates. Highly specific rabbit antisera to IgG and IgM will have either alkaline phosphatase or galactosidase enzyme attached to it. The plates or tubes will be layered over with human allergic sera obtained at various times during allergen immunotherapy.

They will be washed and then relayered with "labeled" anti IgG or IgM. After incubation the plates or tubes will be washed. A solution containing the proper substrates for the enzyme will be added to the plates. The enzyme driven reaction will cause a colorimetric change in the solution. The results will be read visually and in a spectrophotometer. The results will be compared to the radioimmunoprecipitation method which will be performed in the usual fashion. The human sera used has been previously obtained and evaluated by the radioimmunoprecipitation at Fitzsimons Army Medical Center.

PROGRESS

Materials on order.

STATUS: Ongoing

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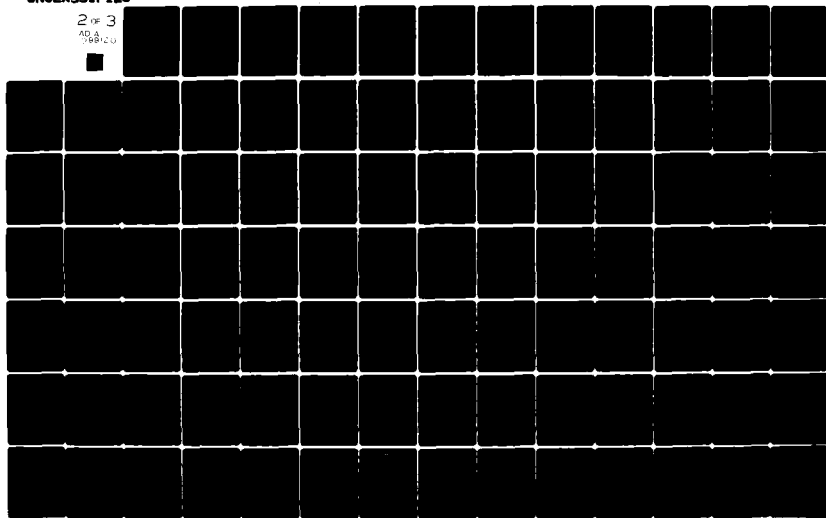
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DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAILS

Assessment of Hematologic and Neurologic Abnormalities in the  
TITLE: Young Alcoholic Patient

WORK UNIT NO: 80/26

PRINCIPAL INVESTIGATOR: LTC P. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if hematologic abnormalities exist in the young alcoholic population in the absence of liver disease or severe nutritional deficiency. To determine the degree of intellectual impairment and presence of peripheral neuropathies especially in the young alcoholic patient.

TECHNICAL APPROACH

All patients admitted for alcohol detoxification or alcoholic liver disease will be considered study subjects. No invasive procedures such as bone marrow biopsy or liver biopsy will be proposed as part of the study. However, if the patient's physician obtains such a biopsy, we will use the data. CBC, SMA 12, serum folate and blood smear will be obtained routinely. Patients who are anemic will have a red cell folate and serum Fe and IBC also collected, and other studies as indicated to evaluate the anemia. In addition to the above routine evaluation, the patients will be asked to consent to the following: (1) Liver sonogram study, (2) Clinical examination by neurologist, (3) Cranial C.T. Scan (when machine is available at WBAMC), (4) WAIS Test (Wechsler Adult Intelligence Scale). Most patients consent to enter the Day Care Treatment Center for two weeks after admission for detoxification. Ideally this will be the period of time when studies are obtained.

PROGRESS

Rapid accrual of study subjects is being realized. All phases of the study are running well.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Use of a New Multitest Applicator in the Evaluation of  
the Clinical Efficacy of Allergen Immunotherapy

WORK UNIT NO: 80/28

PRINCIPAL INVESTIGATOR: LTC L.E. Mansfield, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To assess the value of using a new device called the multitest in the use of serial skin tests to monitor the efficacy of allergen immunotherapy.

TECHNICAL APPROACH

Thirty adult patients who are to begin immunotherapy will be entered into the study. The nature and the purpose of the study will be explained to them.

Each patient will have an immunotherapy set prepared for them. This will be that which is clinically indicated for them. On the day when they begin their immunotherapy program, they will have a specimen of blood drawn. They will be tested by the prick-puncture and by the multitest device to the following: 10 serial dilutions 1:200 to 1:200,000 for their treatment mixture; dilutions of 1:100 to 1:100,000 of either ragweed or Russian thistle allergen (depending upon the patient's sensitivity). The multitest device will be placed so that the top part of the device touches an imaginary line drawn through the points of the scapula. A template will be used to assure a constant location for the titrated puncture test. For uniformity prick-puncture test will be done on the right side of the back two inches from the spine. The multitest will be on the left side of the back two inches from the spine. The serum obtained prior to immunotherapy and at maintenance will be evaluated for the presence of IgE, IgG, and IgM specific antibody to ragweed and/or Russian thistle allergen.

PROGRESS

The initiation of this study awaits order of the materials.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Direct and Indirect Radionuclide Cystography in the Detection of  
TITLE: Vesicoureteral Reflux

WORK UNIT NO: 80/31

PRINCIPAL INVESTIGATOR: LTC H. Henry, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To detect and quantify vesicoureteral reflux.
2. To provide early detection of any deterioration in renal function.

TECHNICAL APPROACH

Patients with known vesicoureteral reflux will be studied by computerized radionuclide renal imaging and direct radionuclide cystography. The radioactive pharmaceutical used will be  $^{99m}\text{Tc}$ -MTPA. These studies will be performed on the child's regularly scheduled followup visit to the Urology Clinic, in lieu of further radiographic examinations. A flow sheet will be completed on each child that is studied and copies retained by the Nuclear Medicine and Urology Service.

PROGRESS

Of six patients studied the direct method shows greater sensitivity for detection of reflux than comparable radiographic studies, i.e. IVP and retrograde cystogram.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: A Randomized Trial of Chemotherapy and Radiation Versus  
Radiation Alone in the Treatment of Advanced Non-small Cell  
Lung Cancer

WORK UNIT NO: 80/32

PRINCIPAL INVESTIGATOR: LTC P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the efficacy of combination chemotherapy with 5Fu, Vincristine and Mitomycin as measured by response rate and survival benefit in patients with advanced non-small cell lung cancer.

TECHNICAL APPROACH

The details are lengthy and specified in the original protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

This protocol has been forwarded to the Clinical Investigation Review Board, HSC, for review. Approval had not been received at the end of FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Effects of Beta -2-Adrenergic Agents in Immunoglobulins

WORK UNIT NO: 80/33

PRINCIPAL INVESTIGATOR: LTC Lyndron E. Mansfield, MC

ASSOCIATE INVESTIGATORS: Robert Frederick, PhD, DAC

OBJECTIVES

To establish in an animal model if the effects of beta-2-adrenergic agents on immunoglobulin levels are due to defects of synthesis or increased catabolism.

TECHNICAL APPROACH

Laboratory white rats will be used for this experiment. They will be grouped in units of ten animals according to the following plan.

- a. Control groups; no medication
- b. Terbutaline 125 mcg/kg twice daily for 4 weeks
- c. Terbutaline 200 mcg/kg twice daily for 4 weeks
- d. Terbutaline 500 mcg/kg twice daily for 4 weeks
- e. Isoproterenol 375 mcg/kg twice daily for 4 weeks

One week prior to beginning medications all animals will be immunized with human gamma globulin (HGG). Just prior to beginning the medication blood will be drawn and IgG, IgM, and IgA levels will be measured. Antibody titer to HGG will be determined. On the seventh day of the medication regimen the rats will be given a booster of HGG along with a primary immunization of KLH. After the fourth week of therapy the rats will have blood taken for the determination of immunoglobulins, secondary response to HGG and primary response to KLH. Immunoglobulins will be measured by passive hemagglutination and radial immunodiffusion. Antibodies will be determined by passive hemagglutination.

PROGRESS

The materials and biologicals for this study are presently on order. It is expected that the study will begin soon.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7965 Treatment of Early Squamous Cell Ca of the Head and Neck with Initial Surgery and/or Radiotherapy Followed by Chemotherapy vs No Further Treatment Phase III

WORK UNIT NO: 80/35

PRINCIPAL INVESTIGATOR: LTC P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if the disease-free interval and survival of patients in high risk categories of squamous head and neck cancer can be improved by adjuvant methotrexate after initial surgery, radiotherapy or both have resulted in no clinically evident disease (N.E.D.)

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

No patients were entered in FY80.

STATUS: Ongoing



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7902 Combined Modality Therapy with Chemotherapy Radio-  
therapy and Surgery in Advanced Previously Untreated (unresectable)  
TITLE: Stage III & IV Epidermoid Cancer of the Head and Neck Phase III

WORK UNIT NO: 80/36

PRINCIPAL INVESTIGATOR: LTC P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To compare the survival of Stage III and IV squamous cell carcinoma of the tongue, oral cavity, tonsil, oropharynx, hypopharynx and larynx subjected to radiation therapy followed by surgical excision if possible, versus survival of patients subjected to chemotherapy with Cis-Platinum, Oncovin, and Bleomycin (COB), followed by radiation therapy and surgical versus radiotherapy and head and neck surgery.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

No patients were entered in FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7808 Combination Modality Treatment for Stage II & IV  
TITLE: Hodgkins Disease MOPP #6, Phase III

WORK UNIT NO: 80/37

PRINCIPAL INVESTIGATOR: LTC P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a PR at the end of 6 cycles of MOP-BAP.
2. To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission duration over a no further treatment group when CR has been induced with 6 cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

Two patients treated by us remain in complete remission.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

SWOG 7983 Radiation Therapy in Combination w/CCNU in Patients  
TITLE: with Incompletely Resected Gliomas of the Brain Grade I & II,  
Phase III  
WORK UNIT NO: 80/38

PRINCIPAL INVESTIGATOR: LTC P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. The major objective of this study is to compare the survival of patients with incompletely resected Grade I and II gliomas treated with radiation alone versus radiation and CCNU.
2. To compare the effectiveness of radiation therapy versus radiation therapy plus CCNU for remission induction and duration of remission. Because many of these patients will have poorly or non-measurable disease this will only be a secondary objective.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WRAMC, and are available upon request.

PROGRESS

One patient was entered in FY80.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: SWOG 7985 Combined Modality Treatment for ER-Breast Cancer Phase III

WORK UNIT NO: 80/39

PRINCIPAL INVESTIGATOR: LTC P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare disease-free interval and survival among control group Stage I (and Stage II node negative) breast cancer patients whose tumors are determined to be ER- at the time of mastectomy, versus Stage I (and Stage II node negative) ER- patients treated with adjuvant CMFV for 6 months.

To document recurrence patterns among untreated patients with Stage I breast cancer whose tumors are determined to be ER- at the time of mastectomy.

TECHNICAL APPROACH

The details are lengthy and specified in the original SWOG protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

No patients were entered in FY80

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Exercise Induced Asthma in Basic Trainees

WORK UNIT NO: 80/40

PRINCIPAL INVESTIGATOR: LTC S.R. Smith, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

This study is undertaken to determine the incidence of exercise induced asthma in basic trainees. The study will attempt to identify these individuals by pulmonary function testing and the American Thoracic Society questionnaire.

TECHNICAL APPROACH

Each BCT recruit will fill out an ATS-DLD 78 questionnaire regarding his family, personal and medical history. Standardization of this questionnaire has previously been accomplished. While being held in the reception station, Fort Bliss, each recruit will undergo pulmonary function testing. Those individuals with subtle spirometric abnormalities (i.e. reduced mid and terminal flows) or with a mild obstructive ventilatory defect will undergo exercise testing. For the purposes of this study the grading system devised by the Committee on Pulmonary Physiology, American College of Chest Physicians will be followed. Although extensively used as clinical recommendations, the sensitivity and specificity of the questionnaires and pulmonary function tests are conjectural. Statistical analyses will follow available guidelines. Exercise testing will be carried out on a bicycle ergometer. Exercise workloads will be increased 25 watt seconds each minute. During the last 15 seconds of each minute period, the heart rate, minute ventilation will be determined. Expired gas analysis will also be performed. The test will be continued until a heart rate of 80% of the age adjusted maximum heart rate is attained or until the patient fatigues. During exercise, oxygen saturation will be monitored with an ear oximeter. If oxygen saturation drops below 75%, the study will be stopped. Spirographic tracings will be done at 5, 15 and 25 minutes after cessation of exercise as well as at 10 minutes after inhaled bronchodilators. After basic training, all individuals will again complete the ATS-DLD questionnaire. Any individuals with new symptoms will be re-evaluated. Retrospective analysis of preinduction pulmonary functions and questionnaires will be carried out to determine if any single factor predicts exercise induced asthma during basic training. Pulmonary function tests will be compared with the normals established by the VA-Army study.

PROGRESS

This protocol was submitted and approved late in FY80 and patient entry has just begun.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMED MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

WRAMC 7810 Prevention of Gonadal Damage in Men Treated with  
TITLE: Combination Chemotherapy/Radiotherapy for Hodgkins Disease and  
nonHodgkins Lymphomas

WORK UNIT NO:80/41

PRINCIPAL INVESTIGATOR: LTC P.C. Farley, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To prevent permanent infertility and alterations in normal sexual function caused by combination chemotherapy in the treatment of Hodgkin's disease or nonHodgkin's lymphoma.

TECHNICAL APPROACH

The details are lengthy and specified in the original WRAMC protocol. Duplicates are kept on file in the Clinical Investigation Department, WBAMC, and are available upon request.

PROGRESS

This protocol was approved near the end of FY80 and patients have just begun to be entered.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Umbilical Cord Lactate, Pyruvate, Betahydroxy Butyrate,  $pO_2$   
TITLE:  $pO_2$ , and pH Value in Normal and Abnormal Pregnancies

WORK UNIT NO: 74/01

PRINCIPAL INVESTIGATOR: LTC W. Daniell, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the effect of labor on normal pregnancies and pregnancies complicated by placental insufficiency.

TECHNICAL APPROACH

Maternal amniotic fluid, venous, umbilical arterial and umbilical venous blood samples will be studied for the above levels. The results will be correlated with neonatal outcome and morbidity.

PROGRESS

Although this project has been suspended a prolonged time it is still considered worthwhile and will be conducted if conditions permit. The original principal investigator has retired and a new investigator has assumed the project.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Maternal and Fetal Plasma Levels of Steroid Hormones in  
TITLE: Normal and Pathological Pregnancies During Labor

WORK UNIT NO: 74/16

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if a rapid assay of steroid hormones would be of clinical value if drawn at the onset of labor from maternal vein or fetal scalp.

TECHNICAL APPROACH

Women in labor with a high risk for fetal distress from placental insufficiency will be included as samples upon admission to labor and delivery. The radioimmunoassay for estriol is being modified by eliminating some steps and increasing the temperature during incubation.

CONSUMABLE SUPPLIES

\$78

PROGRESS

No additional patients have been entered. No further publications after the FY79 report have been submitted.

STATUS: Completed



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Estriol Production Rate Studies in Pregnant Women

WORK UNIT NO: 76/29

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Determination of estriol production rates in normal pregnant women and correlation in abnormal gestations with the clinical outcome.

TECHNICAL APPROACH

Estriol production rates will be estimated by the infusion of deuterated estriol into these women followed by subsequent serum sampling. A measurement of the amount of deuterioestriol present in extracted estriol samples relative to the total amount of estriol extracted would indicate the rate of endogenous estriol synthesized by the patient.

PROGRESS

None.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Correlation of Amniotic Fluid Cortisol and the Free Estriol  
TITLE: Surge in Maternal Plasma

WORK UNIT NO: 76/34

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To confirm the amniotic fluid cortisol levels at varying gestational ages. To correlate these levels with the maternal free estriol surge and the amniotic fluid L/S ratio and attempt to determine if the cortisol increase is also nonlinear and, if so, if it precedes or follows the free estriol surge.

TECHNICAL APPROACH

The amniotic fluid cortisol concentration and L/S ratios on each specimen submitted will be determined, as will plasma free estriol and cortisol when each amniocentesis is performed. The indications for amniocentesis will be based on currently accepted clinical criteria and the decision for the procedure will be made by attending and resident staff managing the patient. The analyses will be done by radioimmunoassay and TLC as presently performed in the RIA laboratories. The data will be subjected to regression analysis and appropriate rank correlation.

PROGRESS

Sixty-two study specimens were analyzed and the data presented at the Armed Forces District Meeting of the American College of Obstetrics and Gynecology in October 1977. A manuscript has been submitted to Acta Obstet Gynecol Scandinavia.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
FLEXA, TEXAS 79920

DETAIL SHEET

Ultrastructural Investigation of Prostaglandins and Their  
Precursors in the Human Fetal Chorionionic Membrane

DATE: 11/11/77

PRINCIPAL INVESTIGATOR: H.C.W. Daniell, MD

ASSOCIATE INVESTIGATORS: B.J.L. Reimann

OBJECTIVES

To determine if prostaglandins and their precursors can be localized in fetal membrane and to detect any change with these in association with labor.

TECHNICAL APPROACH

Using indirect antibody labeling technique, prostaglandins were tagged at a cellular level. The section was then imbedded and ultrathin sections made.

PROGRESS

Within the constraints of available personnel, research on the location of prostaglandin  $E_2$  was resumed. The work is mainly concerned with the negative controls of the immunohistochemical reaction in human fetal membranes. This work is presently progressing slowly.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Inhibition of Premature Labor with Terbutaline

WORK UNIT NO: 77/04

PRINCIPAL INVESTIGATOR: LTC W.C. Daniell, MD

ASSOCIATE INVESTIGATORS: COL L.L. Penney, MD

OBJECTIVES

To study inhibitory effects of terbutaline on premature labor.

TECHNICAL APPROACH

Patients with no contraindicating condition, such as ruptured BOW, intrauterine sepsis, or abruptio placenta will be treated for premature labor with either Terbutaline or a placebo. After admission to the Labor and Delivery Suite, the following procedures will be initiated:

Terbutaline should be begun 0.25 mg subcutaneously every 3 hours. This dose may be increased up to 1.0 mg subcutaneously every 3 hours as long as severe maternal tachycardia, hypotension or fetal distress do not result. When contractions are stopped, the dose and frequency should be reduced until patients are on 0.25 mg of terbutaline every 4 hours. Once they have been stable for 12 hours, they may be begun on oral terbutaline, 2.5 mg every 4 to 6 hours to maintain control. At this point, the patient may be transferred from Labor and Delivery to Ward 4-P. Patients still having some uterine activity on this dose of oral terbutaline may be increased to 5.0 mg of terbutaline every 4 to 6 hours if tolerated. The oral terbutaline should be continued until 36 weeks estimated gestational age is reached, at which time it should be discontinued.

PROGRESS

Patients under this revised protocol, recently approved by OTSG, will be entered in FY81. A new principal investigator has assumed this protocol.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Study to Determine the Ability of Amniotic Fluid to Inhibit  
Growth of E. Coli

TITLE:

WORK UNIT NO: 77/06

PRINCIPAL INVESTIGATOR: COL David Boyce, MD

ASSOCIATE INVESTIGATORS: LTC M. Sellers, PhD; COL A. Killam, MD

OBJECTIVES

To devise an improved laboratory method for determining the  
inhibitory property of amniotic fluid.

TECHNICAL APPROACH

The growth and/or inhibition of a laboratory strain of E. Coli in  
amniotic fluid as well as certain controlled media is to be  
monitored by a technique using C14 tagged glucose in the various  
culture media and monitored by the amount of 14 O2 eluted as  
measured in a liquid scintillation counter. Maternal and cord  
blood serum zinc levels will be determined as well as the zinc  
and phosphate ratios of the amniotic fluid. An attempt will be  
made to correlate the inhibitory or noninhibitory effect of  
amniotic fluid on the E. coli as well as the zinc and zinc/phosphate  
ratios of this inhibitor effect to neonatal sepsis.

CONSUMABLE SUPPLIES

\$1890

PROGRESS

A presentation of preliminary data was made at the Armed Forces  
District-American College Obstetrics-Gynecologist in October 1978.  
In addition to the manuscript previously excerpted in this report  
a letter to the editor of the J. Nucl. Med. has been submitted.  
Work is currently in progress to isolate the peptide(s) responsible  
for the bacterial growth, or metabolic, inhibition.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Effect of Prostaglandin Synthesis Inhibitors on Uterine Blood Flow

WORK UNIT NO: 77/19

PRINCIPAL INVESTIGATOR: LTC W.C. Daniell, MC

ASSOCIATE INVESTIGATORS: B.F.F. Reimann

OBJECTIVES

Determine effects of prostaglandin synthetase inhibitors on uterine blood flow in pregnant animals.

TECHNICAL APPROACH

Application of three different categories of agents will be considered. The response of the uterine blood flow to specific arachidonic acids, prostaglandin synthesis intermediates, and prostaglandins. This is important because of the necessity to learn in what way the uterine blood flow is influenced by each class of compounds. The response of the uterine blood flow to substances with a known ability to block prostaglandin synthesis (e.g. acetylsalicylic acid or indomethacin). The response of the uterine blood flow to substances of unknown ability to block prostaglandin synthesis (e.g. phenylbutazone) or to substances which have shown, in varying studies, different reactions and consequently have yielded contradicting interpretations. Here particularly the cannabinoids must be included. Drugs to be tested in the study include: 1) estradiol (known to increase the uterine blood flow) 2) indomethacin (known to reduce the uterine blood flow) 3) acetylsalicylic acid 4) phenylbutazone 5) cannabinol (CBN) 6) cannabidiolic acid (CBD acid) 7) (-)-trans- $\Delta^8$  tetrahydrocannabinol (delta-8-THC) 8) cannabidiol (CBC) 10) (-)-trans- $\Delta^9$  tetrahydrocannabinol (delta-9-THC) 11) cannabicyclol (CBCy) 12) olivetol 13) various prostaglandins (PGA, PGB, PGE, PGE family members). Both nonpregnant and pregnant sheep will have electric blood flow monitors implanted around the two uterine arteries. At the same time, catheters will be placed in both the femoral artery and vein with their tips located in the common iliac artery or vein respectively. This surgical procedure is a routine operation of our team (e.g. see Killar, et al, 1973). After recovery of the animals from surgery, the ewes will be given estradiol to increase the uterine blood flow. Doses of indomethacin and acetylsalicylic acid are designed to give an indication of the general reaction norm of each animal. Doses of cannabinoids as indicated above, individually or in combination with other drugs, will be infused into one of the uterine arteries through the first branch of the uterine artery in the broad ligament. The measured parameters as a response to the medication are changes of pressure and flow rate, as recorded through the implanted instruments. The uterine vascular conductance will be calculated from the pressure-flow ratio:

Work Unit 77/19

$$\text{Conductance} = \frac{\text{Flow}}{\text{Arterial-venous pressure}}$$

#### PROGRESS

An attempt was made to measure effects of cannabinoids, indomethacin and aspirin on uterine blood flow in dogs. The flow probe method proved unsatisfactory. Late in FY80  $^{141}\text{Ce}$  microspheres for baseline and  $^{85}\text{Sr}$  microspheres for single point later perfusion determinations were used in pregnant rabbits. This method is limited by being discrete, as opposed to a continuous monitor such as a flow-probe, but is providing reproducible data. Controls have been completed and study of the effects of THC are in progress.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

A Comparison of Phospholipid Levels and Choline Phospho-  
TITLE:transferase (CPT) Activity in Amniotic Fluid and Newborn  
Tracheal Fluid

WORK UNIT NO: 77/25

PRINCIPAL INVESTIGATOR: LTC W.C. Daniell, MD

ASSOCIATE INVESTIGATORS: COL L.L. Penney, MD; David O. Rauls, PhD, DAC

OBJECTIVES

To determine if the level of phosphatidyl glycerol (PG) and phosphatidyl inositol (PI) or the activity of choline phosphotransferase could serve as an accurate index of lung maturity.

TECHNICAL APPROACH

Amniotic fluid, and neonatal gastric and pharyngeal fluids which are normally discarded, will be analyzed for phosphatidyl glycerol, phosphatidyl inositol, choline phosphotransferase, and magnesium. The levels measured will be correlated with the incidence and severity of neonatal respiratory stress and hyaline membrane disease.

CONSUMABLE SUPPLIES

\$1041

PROGRESS

Analysis for PG revealed undetectable levels in 25-day fetal rabbit lung following maternal treatment with either control (saline) or steroid. Further refinement of the PG methodology is being accomplished and additional animals will then be studied.

STATUS: Ongoing



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Comparison of Usual Clinical and Laboratory Measurements of  
Gestational Age with Gestational Age Determined by Radioreceptor

TITLE: Assay (RRA) for HCG

WORK UNIT NO: 78/07

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To confirm the accuracy of pregnancy dating within the first to fourth weeks following ovulation reported by others with the use of RRA for HCG. To correlate this data with other parameters of fetal age as an assessment of the accuracy of these tests which heretofore have relied on subjective, variable gestational age estimates (i.e. menstrual cycle length, LMP, etc.)

TECHNICAL APPROACH

The study will be run as an adjunct to protocol 76/20, with additional volunteers selected from the routine obstetrical clinic. The HCG values will be determined by commercially available RRA. These values will be available only to the principal investigator until the conclusion of the study, at which time the test, if justified, may be instituted as a routine study.

PROGRESS

In establishing baseline data for this protocol, serum estriol, an accepted laboratory parameter of gestational age, has been re-evaluated. The work regarding the unconjugated fraction was reported last year. Three additional manuscripts have been submitted and the abstracts are reproduced below:

1. Estimation of Gestational Age and Maternal Serum Steroid Concentrations: Total Estriol.

Acute increases in maternal serum unconjugated estriol between 35 and 37 weeks of pregnancy have been reported to correlate predictably with gestational age. In this study total estriol was measured by radioimmunoassay in an effort to define maturational surges. Statistically significant variations from predicted regression lines were not demonstrated in any individual patient or in grouped data.

2. Variability in Unconjugated and Total Estriol in Serum During Normal Third Trimester Pregnancy.

We determined unconjugated and total estriol concentrations in serum during the third trimester in 34 normal gestations. Data were obtained weekly for 13 women for as long as nine weeks; 21 others were studied daily for up to 15 days. No correlation between birth weight and either estriol fraction was demonstrated. Between-patient variability was less for unconjugated estriol and was similar for weekly and daily data. Within-patient variability was also less for unconjugated estriol and, as expected, was less for daily than for weekly data. The CV for daily samples, within patient, averaged 13.0% for unconjugated estriol and 20.3% for total estriol. Our data support the daily determination of unconjugated estriol in serum, evaluated for percent changes from single or mean preceding values, as the preferred method of monitoring estriol during pregnancy.

3. Ratio of Unconjugated to Total Estriol in Uncomplicated Third-Trimester Pregnancy.

The serum unconjugated estriol, as a percent of total estriol, has been determined in third-trimester pregnancies studied longitudinally. The unconjugated fraction in any specific sample ranged from 4.1% to 21.6% of the total. The mean percent unconjugated estriol in 34 patients sampled 7 to 15 times each between 32 and 40 weeks of gestation ranged from 5.3% to 13.6%. Higher serum total estriol concentration correlates with a lower percent of unconjugated. The mean percent unconjugated decreases during the last eight weeks of gestation from 11.4% to 8.4% with a calculated regression line of  $Y = 23.323 - 0.368X$ . Thus, the concentration of serum unconjugated estriol is relatively more constant. The majority of patients demonstrate a narrow range of percent serum unconjugated estriol. These circumstances, combined with ease of assay, support the use of serum unconjugated estriol in pregnancy estriol monitoring.

Patients in the first two weeks of pregnancy have not volunteered in sufficient numbers and no more data will be collected.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Acid Aspiration Prophylaxis with Cimetidine, Glycopyrrolate,  
TITLE: and Antacids

WORK UNIT NO: 78/08

PRINCIPAL INVESTIGATOR: LTC W. Daniell, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

This study will determine the relative effectiveness of three different preoperative premedication protocols in reducing the risk of acid aspiration before, during, and after routine surgical procedures.

TECHNICAL APPROACH

The effects of premedication prior to surgery on gastric juice volume and pH will be evaluated in 200 patients undergoing elective nongastric surgical procedures under general anesthesia requiring intubation. Patients taking medications that alter gastric secretion or who have had a history of gastric surgery will be excluded. All patients will be NPO from 2300 the day before surgery. The patients will be randomly assigned to four treatment groups. The data to be analyzed will consist of age, weight, sex, type of premedication, type of surgery, type of anesthesia, length of surgery, observed aspiration, and pH and calculated gastric secretion volume of intubation and extubation collections.

PROGRESS

The staffing shortage in Anesthesia has precluded institution of the study.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

RhoGam Monitoring: FetalDex versus Detection of Circulating  
TITLE: Anti-Rho(D)

WORK UNIT NO: 78/10

PRINCIPAL INVESTIGATOR: LTC M. Sellers, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare testing for anti-D antibody in the serum of Rh negative women receiving human anti-D gamma globulin for the prevention of Rh sensitization with the FetalDex test for fetal RBC in maternal blood.

TECHNICAL APPROACH

FetalDex tests and the standard test to determine if anti-D antibodies are present in the patient's blood 24 to 48 hours after the RhoGam will be done and the results compared. When possible Rh sensitization will be tested for at 6 to 9 months after delivery.

PROGRESS

This project was assumed by Dr. Jane Stafford, CPT, MC, and the data compiled for presentation at the Armed Forces District - American College Obstetrics Gynecology Meeting in FY80. The findings are summarized below:

To date, 58 patients have been tested. (Four patients were excluded from the study because of clotted or incorrectly labeled blood samples). Only one patient by our traditional method required a subsequent dose of Rhogam (her antibody screen was positive after the second vial). The fetalDex study found 11 patients who required more than one vial of Rhogam. One of these required five vials (the same patient who required two by our current method). Twenty percent of those studied would have required more than one vial. Followup studies at six months will be done on any of these patients who are available to test for presence of serum antibody.

The question of the proper way to evaluate candidates for Rhogam dose has been debated previously. Some sources have stated that failure to use a method to quantitate the amount of fetal RBC's in maternal blood (the FetalDex or Kleihauer-Betke) is malpractice. One study retrospectively of 1,630 hospitals' method of detection compared to usage of Rhogam by vial

Work Unit No. 78/10

showed a significant correlation between use of an acid elution technique (Fetaldex) and the use of Rhogam. More than ten times the expected number of patients received multiple vials of Rhogam. This study stated "the possible overuse of Rh immune globulin in some laboratories using Fetaldex is probably due to incorrect interpretation of samples with minimal or no fetal cells." The scientific and legal precedents are not sufficiently established to say that one approach is better than the other. Our current method is cheaper in terms of cost and technician time. In theory, our method protects the patient from the possibility that the antibody supplied has been inactivated, not given properly or was not placed in the vial by the drug manufacturer. To this date we believe our data confirms our belief that the extra expense of the Fetaldex test and the expense of additional Rhogam injections has not been found to be necessary in the treatment of Rh negative patients in our population.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

The Role of Prostaglandins and Prostaglandin Synthetase  
TITLE: Inhibitors in Hemorrhagic Shock

WORK UNIT NO: 78/11

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if prostaglandin levels are increased during hemorrhagic shock and if prostaglandin synthetase inhibitors improve or worsen an animal's condition in hemorrhagic shock.

TECHNICAL APPROACH

Hemorrhagic shock is induced in the standard method of Hardaway. Serial determinations of prostaglandins and the standard physiologic parameters will be followed. Some of the animals will be given a saline placebo, others will be given a prostaglandin synthetase inhibitor.

CONSUMABLE SUPPLIES

\$1142

PROGRESS

Techniques for quantification of the major prostaglandins from plasma are now available in the Clinical Investigation Department, but no animals have been studied to date. The techniques for prostaglandin analysis may be utilized in other protocols, as for example 77/19.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BLAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Inhibition of the Vascular Effect of 17 $\beta$ -Estradiol with  
TITLE: Actinomycin D

WORK UNIT NO: 78/26

PRINCIPAL INVESTIGATOR: COL L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if the vascular effect of 17 $\beta$  estradiol employs the same pathways as the growth promoting effect on the sex organs of rabbits.

TECHNICAL APPROACH

Actinomycin D will be given to rabbits in sufficient dosage to block the growth promoting effect of estradiol 17-beta, which is a potent vasodilator of the uterus as well as a potent growth promoter. If the vascular effect of estradiol-17-beta is not affected nearly as much as the growth promoting effect, this would suggest that the vascular effect does not rely on transcription. Study rabbits will be divided into random groups, all will initially have their ovaries removed. A femoral artery and a carotid artery will be catheterized. Baseline uterine blood flow will be determined by infusing 10-15  $\mu$ Ci  $^{141}$ Ce microspheres in the carotid catheter and sampling from the femoral artery. One  $\mu$ g/Kg of 17 $\beta$  estradiol with labeled uridine will be given and the control animals subdivided for study at hourly (or less if needed) intervals to determine onset of increased blood flow. An infusion of 30-40  $\mu$ Ci  $^{51}$ Cr at these intervals will be used to calculate blood flow. All animals will then be sacrificed and aliquots of uterine tissue for RNA quantitation and label incorporation will be analyzed. The microspheres per gram of uterine tissue and per organ will be determined. Subsequently repeat blood flow studies will be done at the time at which control animals increased their uterine blood flow. These animals will receive actinomycin 4 mg/Kg, cycloheximide 20 mg/Kg, or puromycin 200 mg/Kg 30 minutes prior to hormone administration.

CONSUMABLE SUPPLIES

\$3707

PROGRESS

This study was begun late in FY80. Mean uterine blood in the intact mature rabbit has been determined to be 0.69 ml/min/gm. A decrease to 25-30% of this value is seen by six days post-oophorectomy. Base-

Work Unit 78/26

line flow remain unchanged between six and 69 days postoperatively. In establishing the methodology and appropriate controls to use in determining perfusion at separate times it has been found that  $^{141}\text{Ce}$  at  $t_0$  with  $^{51}\text{Cr}$  at 12 hours yields results at the latter time which are inconsistent.  $^{85}\text{Sr}$  has, however, proven satisfactory as the second isotope. Control animals to establish the validity of the technique, to demonstrate change with each of the planned diluents (propylene glycol, ethanol, saline) and to determine the increase in flow following estradiol administration to the oophorectomized rabbit are being entered.

STATUS: Ongoing



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Distribution of Group B Streptococcus

WORK UNIT NO: 78/27

PRINCIPAL INVESTIGATOR: MAJ R. Heath, MD

ASSOCIATE INVESTIGATORS: Robert Frederick, PhD, DAC

OBJECTIVES

To determine where Group B Streptococci are sequestered in the body of rabbits after intravenous infusion.

TECHNICAL APPROACH

Approximately 24 rabbits will be given Group B strep grown in media containing  $^{32}\text{P}$  phosphate to make the organisms radioactive. The rabbits will be sacrificed at 15 minutes, 1 hour, or at 12 hours after the injection. Half will be given live organisms and half will receive killed organisms. The blood, lung, heart, liver, spleen, brain, bowel (jejunum), adrenal lymph nodes in the mesentery and para-aortic area and thigh muscle will be removed and a portion prepared for microscopic evaluation and autoradiography. The remainder of the organs will be counted in the liquid scintillation counter for radioactivity. The amount of radioactivity in the 15 minute group will be compared with the one-hour and 12-hour groups to see where the majority of the organisms are sequestered immediately after infusion and to see if the radioactivity of the organisms is redistributed from its initial position in the body.

PROGRESS

The principal investigator resigned from the Army. Portions of the study will be pursued, under other protocols, by the associate investigator.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
ILLINOIS MEMORIAL APPEAL CENTER  
CHICAGO, ILL. 60620

DETAIL SHEET

TITLE: Prevention of Post Cesarean Section Infections

WORK UNIT NO: 79-04

PRINCIPAL INVESTIGATOR: LEO E.C. Darnell, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine whether the routine administration of Cephalin will lower the incidence of post-cesarean section infectious morbidity. There is a 30-40% incidence of infectious morbidity if a woman is delivered by cesarean section following labor with ruptured amniotic membranes for longer than six hours. Prophylactic administration of antibiotics to patients undergoing vaginal hysterectomy has significantly reduced the rate of infectious morbidity. It is hoped that an antibiotic regimen can be discovered which will reduce the infectious morbidity associated with cesarean section. The cephalosporins have been used extensively for prophylaxis with vaginal hysterectomy. Cephalin was chosen because a single dose given prior to vaginal hysterectomy has been shown to be at least as efficacious as the standard 3-dose regimen with cephaloridine. Other studies involving antibiotics for post-cesarean section infections have not shown a consistent, significant lowering of morbidity. However, patients not in labor or in labor for long periods of time have been included in these studies. We have selected a very high risk population and will test a 1-dose regimen against a control population. Only those patients who have had ruptured B<sub>0</sub>, labor, and intrauterine monitoring prior to delivery will be entered in the study group.

TECHNICAL APPROACH

When a woman is entered into the study she will be placed into one of two drug regimen groups. A control who gets a single injection of a placebo intravenously at the time of cesarean section, another group who gets a single shot of Cephalin, 1 gram IV at the time of cesarean section. Upon discharge, both the mother's and the infant's charts will be reviewed by a member of the perinatal staff and a listing of all the complications compiled from a data sheet included in the study and the chart itself. Patients with previous allergic reaction to penicillin will not be included in the study.

Group I: Placebo at the time of cesarean section.

Group II: Cephalin, 1 gram IV at the time of cesarean section.

Work Unit 79/04

Additionally, in conjunction with Dr. Boyce's study on the influence of amniotic fluid on bacterial growth, small samples of amniotic fluid will be obtained through the monitoring catheter which is routinely emplaced upon admission to the Labor and Delivery suite. The inhibitory effect of these individual specimens with particular attention to zinc levels, will be related to the ultimate result in infectious morbidity. We hope to define groups of low and high risk, one group benefitting from prophylactic antibiotic therapy, and the other not.

#### PROGRESS

Seventy-two patients have participated in the study thus far. The code will be broken in the near future.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Comparative Phase III Clinical Trial of Collatex Sponge and  
TITLE:Diaphragm with Spermicidal Jelly

WORK UNIT NO: 80/5

PRINCIPAL INVESTIGATOR: COL D. Boyce, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

This is a study to compare the effective contraceptive and acceptance factors of the Collatex sponge with the more conventional diaphragm with spermicidal jelly.

TECHNICAL APPROACH

Each clinic participating in this trial will have a sufficiently large number of patients who desire use of barrier contraceptive methods to enroll at least 60 subjects during a one-year period. A woman will be admitted to the study only if she meets all of the following criteria: 1) 18-40 years of age; 2) generally healthy; 3) no anatomical abnormalities which might prevent successful use of the sponge or diaphragm; 4) sexually active; 5) not known to be infertile or sterile; 6) freely consents to participate in the study; 7) at least two menstrual periods since termination of the last pregnancy; 8) can conveniently return for followup. In evaluating and comparing the diaphragm with jelly and the Collatex sponge, the following criteria will be examined: 1) incidence of accidental pregnancy; 2) incidence of allergic reaction, vaginal infection, and other complications, if any; 3) rates of use discontinuation and the reasons for discontinuation; 4) Ease of use; 5) regularity of use.

PROGRESS

None.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

A Prospective Randomized Study of Vaginal and Abdominal Delivery  
TITLE: of the Low Birth Weight Frank Breech Fetus

WORK UNIT NO: 80/7

PRINCIPAL INVESTIGATOR: LTC W.C. Daniell, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine whether the uncomplicated low birth weight frank breech (LBWFrBr) presentation in labor should be delivered by cesarean section or vaginal delivery in order to minimize maternal and neonatal risks.

TECHNICAL APPROACH

Patients presenting to the labor and delivery suite of each of the participating hospitals with 1) a singleton frank breech presentation; 2) at 28 to 36 weeks gestation or 1000 to 2500 gm; and 3) with a cervical dilatation of 4 to 7 cm, will be considered candidates for the study. Patients with cervical dilatation of less than 4 cm will be managed for threatened premature labor as per the routine of the individual institution. Patients with cervical dilatation more than 7 cm do not provide sufficient time for proper entry into such a study. Type of breech presentation will be established by abdominal x-ray fetogram. Estimated gestational age will be based on LMP, early sizing, when HTS were first heard, quickening and estimated fetal weight. Maternal x-ray pelvimetry will be carried out on all patients to assure adequacy of the maternal pelvis. The patient will be considered a candidate for this study only when the senior resident in consultation with staff attending agree that all the criteria for the study have been met.

PROGRESS

An insufficient number of hospitals participated to make the multicenter study meaningful.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Effect of Terbutaline on Surface Active Phospholipids in  
TITLE: Adult and Fetal Lung

WORK UNIT NO: 80/9

PRINCIPAL INVESTIGATOR: LTC W.C. Daniell, MD

ASSOCIATE INVESTIGATORS: David O. Rauls, PhD, DAC

OBJECTIVES

To determine if administration of Terbutaline affects lung maturation profile in adult dog and fetal rabbit lungs.

TECHNICAL APPROACH

Anesthetized adult beagle dogs will be studied in the first phase of the project. They will be given .5 mgm Terbutaline or placebo in 250 cc of saline over a two-hour period. Tracheal bronchial washings using saline will be done at zero, two, four, and six hours and the washings saved and analyzed for surface active phospholipid content to determine if acute infusion of Terbutaline has affected the phospholipid content in the lungs. In phase two, pregnant rabbits with immature fetuses will be given Terbutaline or a placebo subcutaneously over a 3-day period. The animals will then be sacrificed and the fetal and adult lungs will be studied for surface active phospholipids to determine if a change has occurred.

CONSUMABLE SUPPLIES

\$1040

PROCESS

The data obtained to date is summarized: Terbutaline treatment decreased the L/S ratio acutely (by 1 hour) as compared to the control. The L/S ratio for the treated animal no longer differed statistically from control after four hours. The L/S ratio decreased significantly with time for both treated and control animal. The decrease from hour 1 to hour 4 amounted to a 47% decrease for the control group and a 62.8% decrease for the treated group. This represents a potentially significant deterioration in surfactant quality during the period under anesthesia. This could possibly be explained as an effect of the repeated washing with saline or as an effect of the anesthetic. A manuscript is in preparation and additional studies with fetal rabbit are planned.

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMED MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Comparison of Effect of Fetal Lung Maturation of Premature  
Rupture of Membranes and Terbutaline, a Beta Adrenergic Agent

WORK UNIT NO: 80/13

PRINCIPAL INVESTIGATOR: Dr. L. Vaughn, MD, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study effects on fetal lung maturation of premature rupture of membrane and compare these to patients who are in addition treated with terbutaline.

TECHNICAL APPROACH

Amniotic fluid analysis of L/S and evidence of infection of obstetrical patients between 26 and 35 weeks who have premature rupture of membranes will be compared to similar patients who receive prophylactic terbutaline.

PROGRESS

OTSG disapproved this project.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Transvaginal Absorption of Estrogens in Patients Following  
Pelvic Irradiation

WORK UNIT NO: 80/17

PRINCIPAL INVESTIGATOR: MAJ H. Greenberg, MD  
COL L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To quantitate serum levels of 17 $\beta$ -estradiol and estrone following vaginal application of the appropriate cream in patients who are post-irradiation of the vaginal epithelium.

TECHNICAL APPROACH

Patient volunteers who have received pelvic irradiation for non-estrogen dependent neoplasms will be studied. All estrogen medications will be withdrawn for four weeks. Eight to ten patients will be divided into two groups randomly. One group will receive Premarin 1.25 mg and the other Estrace 2 mg intravaginally. Baseline serum estrone and estradiol concentrations will be obtained and repeated at 30 minutes and at one hour, two hours, four hours, eight hours, and 24 hours following the medication. One week later the groups will be reversed. Insofar as possible, patients will be matched regarding age, diagnosis and amount of irradiation received.

CONSUMABLE SUPPLIES

\$774

PROGRESS

Six patients have been entered to date. The chromatography and subsequent RIA of estrone and estradiol have been standardized and sample analysis will be conducted in FY81.

STATUS: Ongoing



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Placental Levels of 5 $\alpha$ -dihydroprogesterone in Normal Pregnancy  
and Those Complicated by Pre-eclampsia

WORK UNIT NO: 80/25

PRINCIPAL INVESTIGATOR: LTC W.C. Daniell, MD

ASSOCIATE INVESTIGATORS: David O. Rauls, PhD, DAC

OBJECTIVES

To determine if placentas of pregnancies complicated by pre-eclampsia have a different concentration of 5 $\alpha$ -dihydroprogesterone than those of uncomplicated pregnancies.

TECHNICAL APPROACH

Placentas from normal and pregnancies complicated by pre-eclampsia will be studied for their content of 5 $\alpha$ -dihydroprogesterone. After consent has been obtained from patients who are admitted in labor, the placentas obtained at birth will be drained of blood and the membranes excised. They will then be weighed and, using the mass-spectrometer, presence and concentration of 5 $\alpha$ -dihydroprogesterone will be determined. Concentration of 5 $\alpha$ -dihydroprogesterone in pregnancies complicated by pre-eclampsia will be compared to that of normal pregnancies. Twenty patients in each group will be studied initially and the mean levels of 5 $\alpha$ -dihydroprogesterone will be compared by Student's t-test.

CONSUMABLE SUPPLIES

\$300

PROGRESS

Quantitation by gas liquid chromatography mass-spectrometry appears to be feasible. Specimens are being collected.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BLAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

An Investigation of the Effect of Supplemental Oxygen on  
TITLE: Chemically Induced Fat Embolization

WORK UNIT NO: 76/24

PRINCIPAL INVESTIGATOR: COL D.A. Vichick, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine whether or not supplemental oxygen prevents or lessens the potentially lethal effects of chemically induced fat embolization in dogs.

TECHNICAL APPROACH

Clinical observations as well as lung scans are generally accepted as criteria for determination of the presence of fat embolism syndrome. In this study laboratory parameters and lung scans are obtained for a five-day period in beagles following injection of oleic acid. This data is collected from dogs supported on either room air or supplemental oxygen.

PROGRESS

Animal testing was suspended temporarily in order to evaluate preliminary work for possible improvements in technique, including discontinuance of oleic acid for embolization. The facility for nuclear medicine studies in animals has not been completed.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATIONS  
WILLIAM BLANKEN APAC MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Compartmental Pressure Studies as a Determinant for the Need  
for Fasciotomy

WORK UNIT NO: 79/03

PRINCIPAL INVESTIGATOR: COL D.A. Vichick, MD

ASSOCIATE INVESTIGATORS: CPT R.L. Hill, MD; MAJ T.W. Ewart, MD

OBJECTIVES

Trauma (insult) to muscles will be followed by an injury reaction resulting in swelling (interstitial)(intercellular) of the involved muscle or muscles. If the traumatized muscles are contained within a nonyielding compartment, increased intracompartmental pressure can reach a level where it exceeds perfusion pressure (diastolic or venous pressure) although distal pulses may be present. As the pressure within the compartment approaches the systolic pressure of the patient there is no tissue perfusion and the distal pulses are absent. Studies in dogs have shown that the tissue injury increases as the duration of the ischemia increases. The impedance of capillary flow and venous drainage will set a stage for increased swelling followed by increased venous blockage until the intracompartmental pressures can exceed the arterial pressure in the small vessels of the involved muscles. The state of ischemia caused by the increase in intracompartmental pressure can lead to necrosis and death of the involved muscles.

Clinical experience has demonstrated the ability to prevent muscle necrosis as a result of increased compartmental/intracompartmental pressure by performing a fasciotomy thus converting the closed and nonyielding space to an expandable area. The clinical parameters of compartment syndrome are: (a) Increased circumference of the extremity. (b) Increased pain of the involved area out of proportion to the injury and accentuated by voluntary motor effort. (c) Decreased motor power of the involved muscle group. (d) Decreased distal sensation. (e) Decreased quality of distal pulses.

The clinical criteria for a fasciotomy do not possess a high degree of sensitivity in indicating the necessity for fasciotomy. Thus errors of omission (delaying fasciotomy too long) and commission (performing fasciotomy when it is truly not needed) are still more frequent than desirable. It has been determined by Whitesides, et al., that as tissue pressure readings equal or exceed 30 millimeters of mercury, the patient must be carefully followed with periodic tissue pressure readings and monitoring of all signs and symptoms of a closed compartment syndrome. Further, as tissue pressures approach or equal the patient's diastolic pressure, a fasciotomy is definitely indicated. Tissue pressure of 40-45 mm of mercury should usually be the upper limit prior to fasciotomy when the diastolic pressure is in the range

Work Unit 79/03

of 70 mm of mercury. It was found that tissue recovery is essentially complete after four hours of ischemia, but only 50% complete after six hours of ischemia. The damage is extensive and irreversible after eight hours of ischemia. The contained neurotissues are even more sensitive to ischemia than muscle and thus the duration of ischemia is even more critical following prolonged increase of intracompartmental pressures.

A study will be conducted in which intracompartmental pressures of the anterior and posterior compartments of the legs, anterior and posterior compartments of the forearm, and dorsal interosseous compartments of the hand will be measured in various states of normal, stress and following disease or injury. The intracompartmental pressure values will be correlated with the clinical picture (pain, increased circumference, decreased motor activity and/or sensation, and quality of distal pulses). When possible and feasible, the uninjured extremity will be used as a control. During this study, fasciotomy will be performed using the accepted clinical indications without regard to the values as determined by the intracompartmental pressure studies alone.

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Three categories of patients will be tested, each group consisting of 25 but not more than 50 patients. The categories will be as follows:

Group 1 - Normal volunteers (or noninvolved extremities of Group 3 patients).

Group 2 - Volunteers who will perform strenuous physical activity with the involved extremity while compartmental pressures are monitored: before, during and after activity.

Group 3 - Volunteer patients who by way of disease or injury are suspected of having increased compartmental pressures of the lower leg, forearm, or dorsum of the hand.

A 22 or 24-gauge intracath will be inserted into the compartments to be studied or in question, both in the lower and upper extremity following a sterile preping of the area. The site selected for insertion will be determined by the investigator. The areas where muscle is felt to be compromised or to be normal will be studied primarily. Areas that closely surround fractures or known hematomas will be avoided if possible. The exact technique for recording intracompartmental pressures will be the same as described by Matsen et al. During the study, the compartment pressures will be obtained and correlated with the clinical picture, a determination will be made as to whether intracompartment pressures offer a significant advantage in determining the need for fasciotomy over known clinical parameters. The risk of the study to the volunteer participants is considered to be minimal and no greater than would occur with any intramuscular injection with a small bore needle.

#### PROGRESS

Appropriate equipment did not arrive until late in FY80. Patient accessions have begun.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Effects of Tourniquet Ischemia on Systemic Coagulation Mechanism

WORK UNIT NO: 79/10

PRINCIPAL INVESTIGATOR: CPT K.J. Guidera, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Determine if there are any abnormalities of the clotting mechanism created secondary to an extremity being under tourniquet ischemia during surgery.

TECHNICAL APPROACH

The effect of surgical tourniquet ischemia has been investigated by multiple authors. Wilgis investigated the effects of this procedure on serum pH, pO<sub>2</sub>, specific gravity and serum solids. Other authors such as Dahlback and Paletta have studied the histological changes in striated muscle when under such a tourniquet compression.

The specific purpose of this investigation is to determine whether an altered state of coagulation is being produced secondary to surgical tourniquet ischemia. Several tests will be done to include platelet counts, clotting times, fibrinogen levels, CPK isoenzyme levels, fibrin degradation product levels and in some cases measurement of clotting factor levels. In black patients, the sickling test will be performed.

The subjects of this study will be adult active duty, retired, and dependent patients undergoing elective hand surgery. Children and lactating or pregnant women will not be studied. No medication will be administered to these patients other than routine preoperative and intraoperative anesthetics. This study does not involve the use of medication. The patients will serve as their own controls. The phases of this investigation will include preoperative clotting studies, intraoperative venous blood samples while the surgical tourniquet is inflated, and postoperative plasma clotting studies. These samples will be evaluated while the patient is in the hospital and no further followup should be necessary. The forms used to record the data will be standard hospital laboratory reports.

PROGRESS

None reported.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BLAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

The Incidence of Visual-Motor Perceptual Problems in Persons  
TITLE: with Traumatic Hand Injuries

WORK UNIT NO: 79/42

PRINCIPAL INVESTIGATOR: MAJ M.J. Baker, AMSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if persons with traumatic hand injuries have pre-existing visual-motor perceptual problems which may have led to their trauma.

TECHNICAL APPROACH

It is recognized by the Federal Government, school systems, and medical professionals that children may suffer from minimal brain dysfunction and/or developmental disabilities resulting in sensory-motor integration problems or inability to perform classroom and play activities in a manner appropriate for their age. In interviews of individuals with traumatic hand injuries it appears that these individuals may not know where their hands are in space and, therefore, suffer from a visual-motor perceptual problem, a form of sensory-motor integration.

The Slosson Drawing Coordination Test is reported "to screen out individuals suffering from serious forms of brain dysfunction or damage where eye-hand coordination is involved." "A reliability coefficient of .96 was obtained for a group of 200 individuals, aged 4 to 52 years." This test does not screen out individuals with emotional problems due to brain dysfunction nor does it identify individuals with eye-hand incoordination due to a specific visual-motor perceptual problem. The Kinesthesia Test of the Southern California Sensory Integration Test" is intended to measure the capacity to perceive joint position and movement." Although this test is standardized for individuals from 4 to 8 years of age, it is felt to be an indicator of individuals unable to perceive their extremities in space, that is, visual-motor perceptual dysfunction.

a. The specific purpose of this study is to determine if individuals with traumatic hand injuries also have a pre-existing visual-motor perceptual problem as measured by the Slosson Drawing Coordination Test and the Kinesthesia Test of the Southern California Sensory Integration Tests.

b. The number of subjects for the study will be 20 persons with traumatic hand injuries. The age range of these individuals will be

Work Unit 79/42

18 to 30 years of age; they will be active duty military, males and females.

PROGRESS

Work continues on the study. Thirty persons with traumatic hand injuries have been tested; however, only three persons for the control group or persons without traumatic hand injuries, have been tested. Plans are to test approximately 25 persons without hand injuries for the control group, to submit results of testing for statistical analysis, and to write up results for possible publication or presentation.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Evaluation of Antagonistic Knee Flexors and Extensors  
TITLE: During Prone and Supine Resistive Exercises using Electromyography

WORK UNIT NO: 80/6

PRINCIPAL INVESTIGATOR: MAJ Wm. R Smith, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The rehabilitation of post-operative patellectomies at this institution has in the past involved the use of straight leg raising with isometric quadriceps exercises. One significant complication of this approach has been the disruption of the operative repair. These exercises are typically performed with the patient in the supine position. One obvious question which we asked was whether prone exercises would facilitate active joint motion while concomitantly reducing the strain on the surgical site and thus minimize the possibility of rupture of the repair. This type exercise is now being performed and the objective of this study is to ascertain the degree of muscular activity in the antagonistic muscle group (i.e. hamstrings versus quadriceps) with resistive exercise in a supine or prone position utilizing the technique of electromyography.

TECHNICAL APPROACH

A study will be performed in which the quantity of electromyographic activity of the quadriceps and hamstring muscle groups will be monitored while normal volunteers undergo both prone and supine knee exercises with flexion and extension, respectively, against varying weight on their ankles. In addition, both fast and slow extension and flexion will be performed. A TECA Model 4 Electromyograph with a preamplifier arm will be used in the study. The surface cathode electrode will be secured to both the anterior and posterior thigh at the area of greatest muscle bulk (approx. mid-thigh) while the surface anode electrode will be placed approximately 1 1/2 inches distal to the cathode. Then, the two tracings will be displayed on the electromyograph simultaneously. The volunteers (10 in number) will then be asked to perform knee flexion (free and against increasing weights at 10, 20, 30 lbs) and extension while in the prone and supine positions respectively. The volunteers will serve as their own control with the free movement. The grading system of EMG activity will be that used by Basmajian and Murphy. In addition the absolute activity in microvolts will be read from the oscilloscopic output of the TECA EMG and recorded. The data will then be assessed for level of significance using the student's paired t-test.

PROGRESS

A few patients have been studied. Numbers should be large enough to report the data in FY81.

STATUS: Ongoing



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Molecular Etching

WORK UNIT NO: 70/111

PRINCIPAL INVESTIGATOR: B.E.F. Reimann, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To obtain general information on the ultrastructure of biological membranes (in particular the erythrocyte membrane) and other cellular organs in order to discern their structural changes under varying experimental (and disease related) conditions and, for this reason, to develop techniques by which the biological material can be investigated in the least altered state employing methods such as freeze drying and ionic etching in conjunction with electron microscopy.

TECHNICAL APPROACH

The final goal is to subject lyophilized embedded biological material to a bombardment with accelerated ions or atoms and to reveal the obtained structures by electron microscopy. Presently the experiments are primarily concerned with osmotic pressures of erythrocytes employing freezing point depression osmometry and direct measurements with a Pfeffer's cell. A "critical point" drying chamber has been constructed.

PROGRESS

The research conducted by staff of the Electron Microscopy Laboratory and members of the Department of Biology, New Mexico State University on cell walls, cell membranes and the mode of cell division in Mycobacterium avium resulted in a presentation entitled "Factors that Affect the Cell Cycle of Mycobacterium avium" at the International Conference on Atypical Mycobacteria, 6 Sep 79, National Jewish Hospital and Research Center, Denver, Colorado, presented by McCarthy C. (Assoc Prof. New Mexico State University, presenting the paper), Ashbaugh, P. (WBAMC) and French, C. (NMSU) co-authors. This paper is now in press under the same title and with the same authors in Review of Infectious Diseases (Nov-Dec). The principle investigator has participated as advisor only in this work, and consequently does not appear as author. His contribution is acknowledge in the publication. Very little work was done - with the exception of some resin formula combinations - on the actual ionic etching project due to the investigators involvement in establishing a new electron microscopy laboratory in the WBAMC Annex building under construction.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Chemotherapy of Cancer

WORK UNIT NO: 76/07

PRINCIPAL INVESTIGATOR: Dr. J. Swaney, MD

ASSOCIATE INVESTIGATORS: Dr. V. McKie, MD

OBJECTIVES

The association of WBAMC Pediatric Oncology and Hematology Service with the various members of the Southwest Cancer Chemotherapy Study Group, Pediatric Division (through M.D. Anderson Hospital and Tumor Institute), Acute Leukemia Group B, and with the Children's Hospital Oncology Center, Denver, Colorado, in conducting trials of chemotherapy in cancer will (1) obtain the necessary understanding of the cancer process; (2) determine effective therapeutic approaches; and (3) provide needed information to use in the care of children with malignant diseases. The association provides for probing of common knowledge and for better statistical evaluation of processes and results.

TECHNICAL APPROACH

Each protocol used by the various aforementioned groups goes through a rigorous process of review, revision, and evaluation prior to becoming activated for group usage. The flow of protocol from author through specific disease committee, statistician, committee headquarters, studies management board, Cancer Investigation Branch of the National Cancer Institute is the usual process. Data collected by each member is reviewed and analyzed by the individual data sent.

PROGRESS

None reported.

STATUS: Terminated

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT AINSWORTH CENTER  
HOUSTON, TEXAS 77030

DETAILS

The use of Elliott's B solution, sterile as Methotrexate diluent for intrathecal use

DATE INITIATED: 7-1-68

PRINCIPAL INVESTIGATOR: Dr. J. Swanson, MD

ASSOCIATE INVESTIGATOR: Dr. A. Meete, MD

OBJECTIVES

The object of this study is to determine if the use of Elliott's B solution as diluent for intrathecal Methotrexate will reduce the evidence of side effects, i.e., headaches, fever, vomiting, etc.

TECHNICAL APPROACH

Patients are eligible for this study who are receiving intrathecal Methotrexate either as prophylaxis or for treatment of central nervous system leukemia. Stock solutions of Methotrexate will be diluted to a concentration of 1 mg/cc with Elliott's B solution. The dose of Methotrexate shall be calculated at 12 mg/m<sup>2</sup> per dose with a maximum of 15 mg/m<sup>2</sup> per dose. The timing of the intrathecal injection shall be individually determined. Records shall be kept of patient status following injection as regards headache, fever, nausea, vomiting, etc. Response shall be determined by absence of side effects or their diminution if they had been previously present. Possible CNS contamination from injection of foreign material may result in toxicity which may be evidenced by fever, headache, nausea, and/or vomiting following intrathecal injection of Methotrexate diluted with Elliott's B solution. Approximately ten patients per year will be treated on this protocol.

PROGRESS

None reported.

STATUS: Terminated

FINAL REPORT

Project Title: Zinc and Phosphate in Maternal Infant Pairs

Principal Investigator:

Principal Investigator: Dr. J. L. Penney, MD

Principal Investigator:

OBJECTIVES

To determine the zinc level in maternal infant pairs and to see if there is a correlation with the incidence of infection.

TECHNICAL APPROACH

Zinc and phosphate concentrations in maternal and neonatal cord blood will be correlated with the incidence of neonatal sepsis in a blind retrospective study. The hypothesis of increasing zinc and phosphate levels in enhanced amniotic fluid bactericidal activity will be studied.

PROGRESS

Over 1000 samples have been analyzed. Statistical correlation of the data is continuing but is slowed due to inability to retrieve patient records.

STATUS: Ongoing

1. *Chlorophyll a* (Chl *a*)

1. *Journal of the American Medical Association*, 277, 1996, 1000-1001.

1. *Chlorophyll a* (Chl *a*)

It is not possible to compare the results of the two studies directly, because the two studies used different methods of data collection. The results of the two studies, however, are in general agreement. The results of the two studies suggest that the use of a computer-based system for data collection and analysis is a viable alternative to the use of a paper-based system.

THE UNIVERSITY OF CHICAGO

children over the age of six years who have been diagnosed as having a clinical or subclinical case of a new seizure disorder. In all children who have been on long term anticonvulsant therapy, there has been no change in intellectual function. This has been recommended for all children had educational and psychological studies before the onset of their seizure disorder. Testing is now accomplished by Psychology using the WISC-R. The first part of the study has gone slowly because we have had very few cases of new seizures or seizure disorders in children over the age of six years.

WILEY-BLISS

As to lack of interest individuals, this project has been very well accepted. The start of the Child Development Fellowship has received interest, but support from the Psychology staff is not as strong as it is in Psychology.

## APPENDIX

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM PEARL ARMY MEDICAL CENTER  
FORTH WORTH, TEXAS 76120

DETAIL SHEET

Study: Maintenance of Patency of the Ductus Arteriosus in Congenital  
Heart Disease

Study Number: 108-14

Principal Investigator: Dr. William Pearl, MD

Study Number: 108-14

INDICATION

Infants with the ductus arteriosus in infants with congenital heart disease, maintaining prostaglandin until diagnostic studies are completed and surgery can be arranged.

CLINICAL APPROACH

Prostaglandin is the only pharmacological treatment available for treatment of congenital heart disease, such as maintaining patency of the ductus arteriosus in infants with abnormalities in newborn infants. In infants in whom blood is flowing from the aorta through the ductus to the pulmonary artery, a catheter is inserted into the aorta and the ductus arteriosus to the first part of the pulmonary artery, and prostaglandin will be administered at the rate of 0.1 micrograms/kg/min. In infants in whom blood flow is passing from the pulmonary artery to the aorta, a catheter is inserted into the pulmonary artery and beyond the ductus arteriosus, and prostaglandin will be infused at the rate of 0.1 micrograms/kg/min. In the event that the major arteries cannot be catheterized, the infant should be treated with a large vein, and the prostaglandin should be given to the infant. In the event that the infant is not responding to the prostaglandin, the infant should be treated with a large vein, and the prostaglandin should be given to the infant.

RESULTS

The results of the study show that the prostaglandin treatment of congenital heart disease is effective in maintaining patency of the ductus arteriosus in infants with congenital heart disease. The results of the study show that the prostaglandin treatment of congenital heart disease is effective in maintaining patency of the ductus arteriosus in infants with congenital heart disease.

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Detection of Toxin by the Group B Streptococcal (GBS) Organism

WORK UNIT NO: 78/23

PRINCIPAL INVESTIGATOR: MAJ R.E. Heath, MD

ASSOCIATE INVESTIGATOR: Robert Frederick, PhD

OBJECTIVES

To determine if the GBS organism has evidence of producing a toxin.

TECHNICAL APPROACH

Live and killed organisms will be injected into rabbits. CBCs, blood gases, and temperatures will be followed closely. Necropsy specimens will be histologically reviewed.

CONSUMABLE SUPPLIES

\$1243

PROGRESS

The principal investigator resigned from the Army. The abstract published in 1979 represents the final work on this protocol.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Antibiotic Prophylaxis for Recurrent Otitis Media: Comparison  
TITLE: of Sulfasoxizole, Erythromycin, and Placebo

WORK UNIT NO: 78/25

PRINCIPAL INVESTIGATOR: LTC M. Weir, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the effect of chronic administration of oral sulfasoxizole, erythromycin or placebo has upon the number of ear infections in children with a history of recurrent otitis media.

TECHNICAL APPROACH

Children under the age of six years who, upon review of their out-patient chart, have a documented history of four or more ear infections in the preceding twelve months will be considered eligible for the study. Children with previous history of PE tubes, cleft palate or immune disease will be excluded. After informed parental consent, the children will be placed on either sulfasoxizole 25 mgm/kg/dose b.i.d., erythromycin 10 mgm/kg/dose b.i.d., or placebo for a three-month period. During this time the patient will be followed monthly with impedance tympanometry and physical examination. Any new ear infections during this period will be treated with systemic antibiotics for ten days. During the second and third three-month period an alternate drug will be used. Each patient will be followed for nine months and will serve as his or her own control. (Three months on Sulfasoxizole, 3 months on placebo, 3 months on erythromycin) in random order. At the conclusion of the study, the frequency of ear infections in children receiving placebo will be compared to those receiving sulfasoxizole or erythromycin.

PROGRESS

The principal investigator was reassigned and has been replaced by LTC Weir. No patients were entered in FY80. Few pediatricians were comfortable with tympanocentesis, a necessary procedure for patients with recurrences while on antibiotics. Many house officers have been instructed by the principal investigator or Dr. Rhodes (ENT) and a degree of expertise is being achieved.

STATUS: Ongoing



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Measles, Mumps and Rubella Immunity in Military Adolescent  
TITLE: Dependents; Correlation with Immunization History

WORK UNIT NO: 79/12

PRINCIPAL INVESTIGATOR: MAJ A. Butler, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the number of adolescents with serologic immunity to measles, mumps, and rubella and to correlate this with their immunization/disease history.

TECHNICAL APPROACH

In September 1978 U.S. Army Health Services Command requested an immunization survey be conducted to determine the adequacy of the Army Medical Departments dependent immunizations. The impetus for this survey was the Presidential Childhood Immunization Initiative and encouragement from the Surgeon General's Office. The occurrence of large numbers of measles cases in junior and senior high school students has highlighted the need to assess the immunization status of children particularly in the adolescent age group and to provide immunization to those not known to be protected. Nearly one-half of the reported cases of measles occur in teenagers, and fifty percent of reported fatalities from measles occurred in adolescents. At the present time there are only limited data relating to the actual antibody status of a major segment of the population. For obvious reasons we propose to determine serologic immunity to measles, mumps, and rubella and to correlate this information with their disease or immunization history.

Each year in May and August one day is set aside for school and sports physical examinations for dependent children at William Beaumont AMC. Approximately six hundred children are examined on these days. Sera have been collected from one hundred and thirty adolescents, after verbal consent, and a history of their immunization record of measles, mumps, or rubella immunization or disease was obtained. Serologic tests including hemagglutination inhibition titers to measles, neutralization antibody to mumps, and hemagglutination inhibition titer to rubella will be performed with the assistance of LTC R. McScott, MC, Dept Virology, WRAIR, Wash DC. Titers less than 1:4 will indicate susceptibility, greater than 1:4 will indicate immunity.

Work Unit 79/12

These data should provide the proportion of our adolescent population that have serologic immunity to measles, mumps and rubella and indicate the reliability of the history obtained from the patient's immunization record.

#### PROGRESS

One-hundred twenty-six adolescents, 71 males and 55 females, ranging in age from 12 to 18 years (mean 16.2 years), were screened for R-HAI antibody by both the Rubindex and the rubella HAI Kit (Table I). A difference in the prevalence and distribution of antibodies was seen between the two tests. For the purpose of this study only the titers derived from the Rubindex will be reported (Table II).

Of the 126 patients, 18 (14.3%) had no documentation of rubella immunization. One-third of these (6 patients) had no detectable R-HAI antibody, while R-HAI titers of 1:16 to 1:256 (GMT 40.2) were demonstrated in the remaining 12. The sexes were equally distributed among those who did and did not receive immunization.

There were 108 subjects (60 males, 48 females) with documented rubella immunization between 3 and 13 (mean 7.8) years of age: an average of 7.9 (range 1.6 - 9.6) year prior to screening. No one received rubella immunization in infancy, since the vaccine was not available until our youngest subject was 2 years old. Although 108 subjects had been immunized, R-HAI antibody was detected in only 90 (83.3%), with a GMT of 27.7 (range 1:8 - 1:256). Antibody was not found in 18 subjects (16.7%). There was no difference in the prevalence of antibody between males and females (Table III). Fifteen of 18 subjects who had no detectable antibody were immunized more than eight years before screening.

All antibody-negative subjects were re-immunized with rubella vaccine, and sera were obtained from 11 subjects before and 14 days after re-immunization. All of the sero-negative subjects developed R-HAI antibody subsequent to reimmunization, with a GMT of 82.3 (range 1:32 - 1:512). All post-immunization sera from this group were tested for R-IgM (Table IV). Rubella-specific HAI activity sensitive to 2 ME (R-IgM) was found in the 19S portion of the gradient in post-immunization specimens from both subjects not previously immunized.

Reimmunization was also offered to subjects with low titered R-HAI antibody; 12 volunteers provided pre- and post-immunization sera. In these subjects the pre-immunization R-HAI antibody had a GMT of 12 (range 1:8 - 1:32) and a post-immunization GMT of 161 (range 1:64 - 1:512). Post-immunization sera from these twelve subjects were also tested for R-IgM, and none was found (Table IV).

Work Unit 79/12

Sufficient serum was available from six subjects for testing by the Prenatal Disease Bureau of the CDC. There were sera from five previously immunized subjects with titers  $\leq 1:8$ , and one unimmunized subject with a titer of  $< 1:8$ . The presence of R-IgM in the latter serum, and its absence in the other five, were confirmed.

TABLE I

RUBELLA HEMAGGLUTINATION INHIBITION TITERS (R-HAI)

BY TWO METHODS IN 126 PATIENTS

	Reciprocal of R-HAI Titer Number of Patients (Percent)			
Method	<8	8-32	>64	Total
Rubindex®*	24 (19.0)#	68 (54.0)	34 (27.8)	126
Rubella HAI Kit+	42 (33.3)#	72 (57.1)	12 ( 9.5)	126

\*Orthodiagnostics, Raritan, NJ

+Flow Laboratories, McLean, VA

#Statistically significant,  $p < 0.01$ , by McNemars Test

TABLE II

RUBELLA HAI TITERS\* FROM 126 PATIENTS WITH AND  
WITHOUT DOCUMENTATION OF PRIOR RUBELLA IMMUNIZATION

Record of Previous Immunization	Reciprocal	R-HAI Titers/Number of Patients (%)		
	<u>&lt;8</u>	<u>8-32</u>	<u>&gt;64</u>	<u>Total</u>
Positive	18 (16.7)	61 (56.5)	29 (26.9)	108
Negative	<u>6 (33.3)</u>	<u>7 (36.0)</u>	<u>5 (27.7)</u>	<u>18</u>
Total	24 (19.0)	68 (59.0)	34 (27.0)	126

\*Rubindex<sup>R</sup> (Orthodiagnostics, Raritan, NJ)

TABLE III

SEX DISTRIBUTION OF R-HAI TITERS IN  
PREVIOUSLY IMMUNIZED SUBJECTS

Reciprocal of R-HAI Titer  
Number of Patients (Percent)

<u>Sex</u>	<u>&lt; 8</u>	<u>8-32</u>	<u>&gt; 64</u>	<u>Total</u>
Male	12 (11.1)	34 (31.4)	14 (13.0)	60 (55.6)
Female	6 (5.6)	27 (25.0)	15 (13.9)	48 (44.4)
Total	18 (16.7)	61 (56.5)	29 (26.9)	108 (100)

TABLE IV

## RUBELLA SPECIFIC IMMUNOGLOBULINS IN 23 VACCINEES

<u>Sedimentation Coefficient</u>	<u>Specific Immunoglobulin</u>	<u>Immunization and Serologic Status Prior to Reimmunization</u>		
		<u>Unimmunized 1:8*</u>	<u>Immunized 1:8*</u>	<u>Immunized 1:8*</u>
19 S	R-IgM	2	0	0
7 S	R-IgG	2	9	12

\*Rubella hemagglutination inhibition titers.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT APTC CLINICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Developmental Analysis of Heavy and Trace Element Hair Content  
in Normal Children and Children with Attention Disorder

WORK UNIT NO: 80/2

PRINCIPAL INVESTIGATOR: LTC P. LoPiccolo

ASSOCIATE INVESTIGATORS: Dr. Krug  
Dr. Terry Allen (UTEP)

OBJECTIVES

To investigate developmental changes in the influence of heavy and trace elements on the behavior of normal children and children with attention disorders.

TECHNICAL APPROACH

Twenty-five normal children and twenty-five children who have been diagnosed as having an attention disorder with excessive activity will be selected from each of the following age groups: Seven-year-olds, nine-year-olds, and eleven-year-olds. An additional group of nine-year-old attentional-disordered children will be selected who are currently on medication. One tablespoon of hair will be collected from the nape of the neck. Ten mm of hair nearest the skin will be trimmed to provide the sample. Information will also be solicited regarding such areas as the date of the most recent hair washing, use of medication, and diagnostic status. A copy of this information form is inclosed. Achievement information for the normal children will be acquired using the Wide Range Achievement Test (WRAT), while intelligence scores will be computed using the Peabody Picture Vocabulary Test (PPVT). The hair samples will be stored in plastic bags and coded in a manner so that an individual child's name is not associated with the results. Once the required number of hair samples has been acquired, the samples will be analyzed using atomic absorption spectroscopy. Comparisons of each of the element levels for the normal and attention disordered children will be made in order to identify a possible relationship between the levels of certain elements and the performance of certain intellectual activities.

PROGRESS

Our collection of hair samples from William Beaumont AMC children is now complete. One hundred one (101) samples have been collected from 59 hyperkinetic children (approximately evenly divided among the 6-9, 10-12, and 13-19 age groups) and forty-two (42) controls. The control samples are predominantly in the younger age group, and we may add some samples from 18 year olds at UTEP. The samples are presently being analyzed for trace metals.

STATUS: Ongoing



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Investigation of the Concerns, Perceptions and Expectations  
of Parents Coming to the Developmental Evaluation Clinic for  
the first time

DATE INITIATED: 80/27

PRINCIPAL INVESTIGATOR: CPT E. Krug, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To understand the concerns, perceptions and expectations of parents  
whose children have developmental problems, when they come to the  
developmental evaluation program.

TECHNICAL APPROACH

All parents bringing their children to the DE clinic for the first  
time (initial workup) will be asked to complete a questionnaire.  
After 100 questionnaires have been accumulated summary statistics  
will be analyzed to determine (1) the most common source of  
referral to the DE Clinic; (2) the most common questions to  
which parents wanted an answer; (3) the accuracy of parent perceptions  
about the function and capabilities of the DE Clinic; and (4) the  
accuracy of parent perceptions of their child's problem. A followup  
questionnaire will be utilized to determine the correlation between  
parent perceptions/biases and the degree of ease (or difficulty)  
in which DE prescriptions are carried out. It may be that  
compliance with DE suggestions and regimens is related more to  
parent understanding of the problem than to resistance to the mode of  
therapy per se. The acquisition of this information may allow us better  
to meet the needs of our patients and their families in the Developmental  
Evaluation Clinic.

PROGRESS

Approximately 50 questionnaires have been distributed to parents at  
this date. It is planned to distribute 50 more.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Counterimmunoelectrophoresis in Nonsuppurative Otitis Media

WORK UNIT NO: 80/34

PRINCIPAL INVESTIGATOR: LTC M. Weir, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Test the possibility that antigen persists in middle ear fluid after suppurative becomes nonsuppurative otitis media. It is known that 20-30% of middle ear effusions will remain culture positive after the standard course of ten days of antibiotics and even though the fluid on followup examinations has become serous. Further evidence of persistent infection would alter therapy in that initiation or continuation of antibiotics might be indicated. That is, patients who present with serous fluid or develop serous fluid after a standard ten day course of antibiotics may need antibiotic therapy. Twenty to thirty patients will be screened in this pilot study and if persistent infection appears common, a study of extended treatment regimens will be proposed.

TECHNICAL APPROACH

The usual indications for myringotomy and PE tubes include persistent or recurrent suppurative and nonsuppurative otitis media. The duration criterion for persistence of nonsuppurative otitis media is 2-3 months. This, with or without a conductive hearing loss, is the most common indication for the procedure. Patients are normally referred from Pediatrics to ENT for consideration for the procedure. Patient selection will be by the ENT specialist and not by the primary investigator. When the procedure is performed, the middle ear effusions will be aspirated, the aspirate preserved in a mucus trap, and transported to the laboratory for CIE, culture and gram stain. Aspiration is standard and no additional risk will result from this study.

CONSUMABLE SUPPLIES

\$200

PROGRESS

Specimens have been collected for two ears. More patients are being accumulated. An unforeseen problem of obtaining a reagent from out of the country is limiting use of CIE, but should not be a problem much longer.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION,  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Infant Auditory Discrimination of Parents and Stranger

WORK UNIT NO: 77/12

PRINCIPAL INVESTIGATOR: Robert C. Husebus, PhD, CPT, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this research was to determine the extent to which very young infants are able to discriminate parents from strangers of the same sex; the present protocol involved comparison between fathers and male strangers.

TECHNICAL APPROACH

Parents are to be contacted within 1-2 days of birth and the planned research will be briefly described. Those who express interest in the study will be contacted approximately one week later and will be given a consent form. For each comparison (father's vs male stranger, and mother vs father) the reaction of 12 - 15 infants between 1 and 2 weeks of age will be compared.

PROGRESS

There were results from 20 infants which met the criteria of sufficient crying and of sufficient pausing while the adults were speaking to the infants. The major comparison of interest was the extent to which infants would pause from crying more readily to their father's voices than to a male stranger's voice. (Earlier published research revealed that infants discriminated their mother's voices from female stranger's voices and paused significantly sooner when their mothers spoke). Two scorers worked independently and simultaneously to transcribe an event recorded the pattern of cries and pauses emitted by each infant and to each adult. The percent agreement as to which adult the criterion pause occurred first was calculated; in 23 of 24 cases there was agreement - for a 95% rate of agreement. The latencies to criterion pauses for father and stranger were compared by means of t-test for paired comparisons. The results were as follows:  $t = 2.925$ ,  $p = .01$ , a highly significant difference in favor of the fathers. Thus, the infants paused significantly sooner when their fathers spoke to them supporting the conclusion that infants with an average age of 2 weeks can and do differentiate their father's voices from strangers' voices.

CONCLUSION

data are consistent with the aforementioned results, and suggest that mother-infant attachment. Together these studies shed new light on the as yet not fully understood period of early infancy and the beginning of social attachment. These data have been submitted for publication.

LITERATURE CITED

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

The Effect of Instructional Pretraining and Type of Treatment  
on the Acquisition of Assertive Behavior

DATE 78/04

PRINCIPAL INVESTIGATOR: Edward O. Crandell, LT, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of the study is to compare the effectiveness of two methods of psychotherapy (behavioral and insight-oriented) used in conjunction with instructional retraining on development of assertive behaviors.

TECHNICAL APPROACH

A total of 50 volunteer subjects will be selected from among the patient population of the Psychology Service of William Beaumont Army Medical Center in El Paso, Texas. All subjects will be assigned to one of five groups. The purpose of these groups will be to aid each subject in his/her ability to behave assertively and to determine which of the five methods to be used is most effective in teaching this skill. The procedures to be followed and qualifications of the therapists to be used are described in detail in the originally submitted protocol.

PROGRESS

The study investigated the effect of behavior therapy, insight-oriented therapy, and instructional pretraining on the acquisition of assertive behavior. The dependent variables were the expression of positive assertive statements, the expression of negative assertive statements, and the predisposition to respond assertively. The independent variables of type of treatment and type of pretraining were combined in a completely randomized 2 x 2 multifactor design with a fifth group added which received instructional pretraining only. It was hypothesized that subjects receiving behavior therapy plus instructional pretraining would score significantly higher on behavioral and self-report measures of assertion immediately after treatment and 30 days following treatment.

A total of 40 subjects were randomly assigned to one of the five groups, and treatment and control procedures were randomly assigned to the groups. The subjects were post-tested immediately after treatment and 30 days following treatment using behavioral measures

of positive and negative assertion and a self-report measure of assertion. The behavioral measures consisted of a positive assertion score and negative assertion score obtained from the independent ratings of the subjects' responses to videotaped situations and written statements requiring the expression of positive and negative assertion. The self-report measure was the Adult Self-Expression Scale.

Behavior therapy consisted of modeling, feedback, and behavior rehearsal using videotaped assertive problem scenes. Insight-oriented therapy consisted of the identification of assertive problems and the exploration of feelings through the use of empathic responses by the therapists. All treatment was administered individually in four sessions which occurred within two weeks of pretraining. The instructional pretraining procedures consisted of a videotaped presentation containing instructions about the components of assertive behavior and assertive responses. Examples of assertive response were modeled. Subjects receiving only instructional pretraining viewed the videotaped presentation and were post-tested two weeks later.

Results of univariate ANOVA revealed a significant difference,  $p < .01$  among the five groups on the negative assertion score obtained from the videotaped measure immediately following treatment. ANOVA tests for the other dependent measures were statistically nonsignificant. Multiple comparisons of the negative assertion mean scores on the videotaped measure using the Scheffe procedure resulted in a significant difference between groups which received behavior therapy and those receiving insight-oriented therapy. Subjects who received behavior therapy made significantly more negative assertions on the videotaped measure. The influence of instructional pretraining was found to be nonsignificant. Analysis of the assertion scores on the written statements and the adult Self-Expression Scale resulted in no significant differences among the groups immediately after treatment and 50 days following treatment.

The hypothesis that the combination of instructional pretraining and behavior therapy would result in significantly higher scores on the behavioral and self-report measures was not supported. The independent variable which contributed to higher negative assertion scores was the type of treatment received. Subjects receiving behavior therapy made significantly more negative assertive statements on the videotaped measure than subjects who received insight-oriented therapy or instructional pretraining only.

The results of the study supported the use of behavior therapy as a method of treating assertive problems. The use of an instructional pretraining component was not supported. The results questioned the need for specific training in positive assertion. The results were also

Work Unit 78/04

seen as supporting the contention that behavioral measures are more effective discriminators of assertive behavior than self-report measures. It was recommended that future research examine the need for training in positive assertion and that the present study should be replicated using a no-treatment and no-pretraining control group. This data is now being expanded and submitted as a dissertation in partial fulfillment of the Doctor of Philosophy degree in psychology.

STATUS: Completed.

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Inventory Construction Attentional and Thinking Skill  
TITLE: Assessment for Children

WORK UNIT NO: 79/11

PRINCIPAL INVESTIGATOR: MAJ Bentham, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To improve our description of both normal and learning disabled childrens' attentional ability.

TECHNICAL APPROACH

Fifteen children diagnosed hyperactive/learning disabled by our Pediatric Department and fifteen children randomly assigned to attend regular classrooms and are diagnosed to be normal children will form the sample. A task with three different parts will be used to provide a score for each of the specific skills mentioned previously. A modified card sorting task will provide information concerning the child's distractibility, flexibility of attention, and degree of concentration. A stimulus familiarization task will be used to index the child's distractibility and the breadth of attention. A modified version of a vigilant task will be used to indicate the child's distractibility, ability to maintain an attentional set and the degree of concentration. This representation will permit the identification of those skill areas which are weak as well as the child's skills which are satisfactory. A followup study increasing the sample size will be proposed at a future date if significance is found during the proposed study.

PROGRESS

None

STATUS: Terminated



DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Development of a Computerized Trauma Registry

WORK UNIT NO: 76/09

PRINCIPAL INVESTIGATOR: LTC J.P. Collins Jr, MD, and  
1LT William J. Klenke, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To complete development of an automated system for storage, retrieval, and processing of pertinent data for patients with traumatic injury at EBAMC

TECHNICAL APPROACH

A computer program will be written to allow the entering, editing, displaying, sorting, classifying and analyzing of patient information. The patients will be restricted to those who are admitted to the Trauma Ward. These records will be used to analyze the epidemiology of traumatic injury and the effectiveness of therapeutic modalities in the management of injured patients.

CONSUMABLE SUPPLIES

\$596

PROGRESS

The data from years prior to 1980 were coded and saved on the IBM 1400 (located in MIS0) with no means of retrieval or transfer. This data was successfully removed, interpreted, and saved on the Hewlett Packard 9845 computer (located in Dept Clinical Investigation). All data from mid-1980 to the present has been captured by direct or manual entry by the Dept of Surgery. Analysis of these data bases has begun, to determine the validity and completeness of the data. Data concerning the peak hours of utilization, the most common injury, and characteristics of a patient with a specific injury have been examined with regard to increasing efficiency, but this analysis has only been done in a cursory manner. A significant event affecting this protocol this year was acquisition of disk storage devices to expand data storage/processing capabilities.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Pathophysiology and Treatment of Hemorrhagic and Traumatic Shock

WORK UNIT NO: 77/24

PRINCIPAL INVESTIGATOR: LTC J. Collins, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the pathophysiology and treatment of hemorrhagic and traumatic shock and the effect of vasodilation, steroids, and fibrinolysin on these types of shock.

TECHNICAL APPROACH

Disseminated Intravascular Coagulation (DIC) and fatality have been shown to require the presence of slow capillary flow (shock) and the presence of a thromboplastic material in the blood stream. It is proposed to test the efficacy of phenoxybenzamine (an alpha blocking agent), steroids, and fibrinolysin in the prevention of DIC following traumatic shock.

PROGRESS

No additional studies have been done. A publication was reported last year.

STATUS: Completed

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: National Intraocular Lens Implantation Study

WORK UNIT NO: 78/03

PRINCIPAL INVESTIGATOR: MAJ Donald J. Bergin, MC  
MAJ Floyd M. Cornell, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To participate in the study of clinical results of implantations of intraocular lenses organized by the Intraocular Lens Manufacturer's Association in response to directives of the Ophthalmic Classification Panel, FDA.

TECHNICAL APPROACH

An intraocular lens is a prosthetic replacement for the eye's crystalline lens. It is placed in the eye at the time of cataract surgery, where it is fixated by a variety of means, with the intention that it remain permanently and correct the large refractive error remaining after conventional cataract surgery.

PROGRESS

From 1 July 1979 to 1 March 1980 a total of 12 cataract removal surgeries with implantation of intraocular lens have been performed. All patients have been followed as outpatients as required by FDA. The SOP, as presented to the Clinical Investigation Committee, has been followed. There have been six complications in the entire series of 72 patients dating back to 1978.

A 65 year-old female reported in 1978 who developed endothelial decompensation and microcystic edema seven months following surgery. Date of surgery was 29 Nov 77 O.D., and 23 Mar 78, O.S. Patient has undergone corneal transplant on the right eye performed by Dr. Robert E. Sexton, MD, Silver City, N.M. The possibility exists that a corneal transplant may also be required for the left eye.

Sixty-eight year-old male had surgery with implantation of intraocular lens 1 Nov 79 of the left eye. The patient developed corneal edema three days postoperatively, and the lens was removed. The patient is doing well and visual acuity in the operated eye is 20/30.

Work Unit 78/03

- Sixty-five year old male underwent implantation of an intraocular lens on the right eye on 20 Apr 78. The patient developed pseudophakic bullous keratopathy and underwent a penetrating keratoplasty associated with an anterior vitrectomy on 9 Feb 80 at Fitzsimons Army Medical Center. The patient is doing well at this time.

- Sixty-eight year old male underwent intraocular lens implantation of the right eye on 18 Jan 79. The patient has developed cystoid macular edema which is being treated with celestone injections.

- Sixty-two year old female had implantation of intraocular lens on the left eye 23 Feb 78. The patient had recurrent hyphema and decreased vision. The lens was removed surgically on 31 Mar 80. The patient's visual acuity is 20/25 with a contact lens.

- Sixty-four year old female had removal of cataract from the left eye with implantation of an intraocular lens 17 Apr 79. The patient has developed cystoid macular edema which is being treated with injections of steroids. The possibility of removal of the lens is being considered.

There were no undue complications either technically or surgically associated with any of the above cases. The next scheduled annual review is in April 1981.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Perioperative Thrombosis Prophylaxis in Patients with  
TITLE: Peripheral Vascular Disease

WORK UNIT NO: 79/43

PRINCIPAL INVESTIGATOR: LTC J.T. Collins, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the efficacy and safety of low-dose heparin prophylaxis in patients undergoing peripheral vascular surgery.

TECHNICAL APPROACH

Patients entering the hospital for a proximal revascularization (aorto-iliac bypass, aorto-iliac endarterectomy, or aorto-femoral bypass) procedure will be randomly assigned to either a control or a treatment group. Patients in the control group will receive no thrombosis prophylaxis. Patients in the treatment group will receive 500 u of heparin subcutaneously each 12 hours for ten days after the methods of Kakkar and co-workers, and Flanc and co-workers. Heparin given intraoperatively will be reversed in keeping with our usual practice.

Venous thrombosis will be demonstrated using the 125I-fibrinogen leg scans. 125I-fibrinogen is converted to fibrin under the influence of thrombin, thus incorporating 125I into a developing clot.

Commercially available 125I-fibrinogen is a derivative of single-donor human plasma. These donors are carefully screened for blood borne, transmissible diseases, particularly hepatitis. No cases of hepatitis or other illnesses have been reported with the product to be used.

To perform the test, the freeze dried preparation is reconstituted with sterile water at the time of injection. A routine 1 cc dose consists of 2 mgm of clottable protein, and 140 mCi of 125I. All patients will receive 250 mg (5 drops) of saturated KI orally 24-hours prior to injection of 125I-fibrinogen to effect thyroid blockade

125I decays by electron capture with a physical half-life of 60 days. There is no beta emission. Photons are of x-ray (35 KVP) and  $\gamma$  x-ray (28 KVP).

Work Unit 79/43

External radiation is 1.5/mc/hr at 1 cm. Radiation dosimetry is as follows: thyroid (unblocked), 1.5 R/100 Ci; thyroid (blocked), 0.02 R/100 Ci; whole body, 0.02 R/100 Ci.

The administration of  $^{125}\text{I}$ -fibrinogen and scintillation counting for each patient will be performed by the Nuclear Medicine Service, WBSM, under the direction of LTC H.W. Henry, MC. The thrombus detector, to be purchased by the Dept Clinical Investigation, utilizes a thallium activated sodium iodide crystal. Counts will be taken daily beginning 24-hours after injection of the isotope and for a period of ten days unless an abnormal scan is noted. Therefore, the first dose will be given two days before the operation.

The scanning procedure consists of passing the above described hand-held device over the patients' sternum and at various levels of both lower extremities for periods of five to thirty seconds. Venous concentrations of  $^{125}\text{I}$  in the lower extremities correlate well with deep venous thrombosis. The counting device is easily transported, the exam is quick and noninjurious to the patient, and it will be performed at the patients' bedside.  $^{125}\text{I}$ -fibrinogen leg scanning is now a well-accepted procedure in many hospitals.

Accurate documentation of all other thrombotic events will also be sought. Cerebrovascular accident will be diagnosed clinically and confirmation will be sought by vascular and static brain scans. Suspected myocardial infarction will be confirmed by electrocardiogram and serial cardiac enzyme determinations. Patients who develop a positive  $^{125}\text{I}$ -fibrinogen scan will have a phleboreogram performed daily. If the phleboreogram is positive, the case will be judged a failure of prophylaxis, and heparin will be begun by continuous infusion with the goal of keeping the activated partial thromboplastin time at 1.5 to 2.5 times normal. Phleboreography as developed by Cranley and co-workers has been confirmed by us to be 95.3% accurate for detecting clinically significant venous thrombi. Phleboreography is a noninvasive test with no risks to the patient. Suspected pulmonary embolism will be confirmed by chest x-ray, arterial blood gases, pulmonary scans, and pulmonary arteriography when indicated.

All patients will be counselled regarding the various ramifications of the protocol and will sign a human volunteer agreement prior to entry into the study. It is estimated that 100 patients will be entered into the protocol over a two-year period. Data concerning the perioperative management will be available at the end of two years. In the unlikely event that a patient with a contraindication or allergy to heparin should be considered for operation, he will be excluded from the study. Female patients, aged 15 to 50 years, will be screened with pregnancy tests and positive results will serve as a basis for elimination from this protocol.

Work Unit 79/43

Should a hemorrhagic complication develop, heparin administration will be discontinued. Although ecchymoses may develop at the site of heparin injection, the chance of developing wound hematomas or life threatening hemorrhage from low-dose heparin, properly administered, is essentially nil. A thrombin time will be obtained and circulating heparin will be neutralized by protamine if necessary. We will attempt to correlate the eventual outcome with the preoperative profiles.

PROGRESS

This study was not approved by OTSG until mid-FY80. Essential equipment was received at the end of FY80.

STATUS: Ongoing

DEPARTMENT OF DEFENSE INVESTIGATION  
WALLACE H. BROWN ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Effect of Systemic Anti-Neoplastic Chemotherapy on Dacron  
Graft Incorporation

WORK UNIT NO: 80/12

PRINCIPAL INVESTIGATOR: CPT J.R. Daniel, MD  
LTC J.T. Collins MD

ASSOCIATE INVESTIGATORS: LTC T.J. Brown, MD, D. Rauls, PhD

OBJECTIVES

To determine the effect of systemic cancer chemotherapy on the healing events which allow incorporation and formation of a neo-intima in dacron prosthetic grafts.

TECHNICAL APPROACH

Graft incorporation will be followed by platelet survival times. This is an accepted measure of graft incorporation with platelet survival being reduced by 50% immediately after graft placement and returning to normal as the graft is incorporated. Also dogs will be sacrificed at six weeks and six months for histological examination of graft healing. Any dogs which die or develop complications related to the graft will be histologically studied. Graft incorporation will be studied in the following settings: (1) A graft placed simultaneously with initiation of chemotherapy. (2) A graft placement after initiation of chemotherapy. Three controls will be used. In one group platelet survival will be followed without any treatment, to monitor consistency of technique of platelet survival determination. In another group platelet survival will be monitored before and during chemotherapy. A third group will have a thoracoabdominal graft placed without chemotherapy.

CONSUMABLE SUPPLIES

\$5524

PROGRESS

The study calls for a total of five groups of animals plus a control group. A total of 43 animals have had baseline platelet survival times determined using Indium-111 labeled platelets. Six animals have been entered into the control group and platelet survival times are being monitored periodically as called for in the protocol. Four of these have now been followed for one month. Four animals have been entered into Group II (no surgery adriamycin treated). All four have been followed for one month after initiation of adriamycin treatment and two have been monitored for three months. Six animals have been entered into Group III (surgery only) and platelet survival times have



Work Unit 80/12

been monitored for six months following surgery. Six animals have also been entered into Group IV (surgery followed by adriamycin treatment three months later) and all six animals have been monitored for three months post-surgery. These animals are now in the adriamycin treatment phase of the study. Other animals are being entered into the study as time permits. Insufficient results have been obtained at this point to draw any conclusions.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BLAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Physiologic Monitoring and the Manipulation in the Aortic  
TITLE: Reconstruction Patient

WORK UNIT NO: 80/30

PRINCIPAL INVESTIGATOR: LTC J. Collins, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To assess the effects of shock trousers at varying degrees of compression upon the cardiovascular system and patients about to undergo aortic reconstruction, to optimize patient's cardiovascular status in terms of left ventricular stroke work index, peripheral vascular resistance, and cardiac index prior to undergoing major aortic reconstruction and to assess the benefits of this approach in the intra- and postoperative period.

TECHNICAL APPROACH

All patients scheduled for elective aortic reconstruction on the day prior to surgery are admitted to the Trauma Unit or Surgical Intensive Care Unit where Swan-Ganz balloon catheters and arterial lines are placed. Following placement and the base-line determination of multiple parameters outlined in the protocol, shock trousers are placed and varying degrees of compression applied. At each level of compression these parameters are remeasured. Following this, the trousers are removed and varying amounts of lactated Ringers solution is administered intravenously and the effects of intravenous infusion on the cardiovascular parameters are determined. Following achievement of "optimum" cardiovascular parameters, the patient is considered prepared for surgery and subsequently undergoes the scheduled aortic reconstructive procedure.

PROGRESS

To date eight patients have undergone the complete protocol. An additional twelve patients have undergone portions of the protocol, and information is available to coordinate the overall results. Our goal was twenty patients to be carried through the formal protocol, at which point results of the approach will be tabulated and assessed. At this point, because of the relatively small number of patients having completed the protocol, deductions regarding clinical application of this procedure cannot be made with any certain validity.

STATUS: Ongoing

DEPARTMENT OF CLINICAL INVESTIGATION  
WILLIAM BEAUMONT ARMY MEDICAL CENTER  
EL PASO, TEXAS 79920

DETAIL SHEET

Pilot Study for the Use of the Automated Autologous Blood  
Recovery System (Cell Saver) in Blunt and Penetrating Abdominal  
Trauma

DATE INITIATED: 80/42

PRINCIPAL INVESTIGATOR: LTC J.T. Collins, MD

ASSOCIATE INVESTIGATORS: CPT J.A. Camunas, MD; CPT T.E. Gaines, MD;  
COL A. Kissack, MD

OBJECTIVES

To establish the effectiveness of the automated autologous blood recovery system (cell saver) in providing an economical, efficient, safe source of autologous red blood cells for patients undergoing elective surgical procedures and in decontaminating free peritoneal blood associated with blunt and penetrating thoracic and abdominal trauma.

TECHNICAL APPROACH

The automated autologous blood recovery system will be used in trauma patients presenting with either blunt or penetrating abdominal or chest trauma. In addition, all patients undergoing elective thoracic, gastrointestinal, and vascular surgical procedures in which significant attendant blood loss is anticipated will be included in this study. Intraoperatively, aerobic and anaerobic blood cultures and gram stains of the free intrathoracic and peritoneal blood will be obtained. The autologous blood recovery system will be used in recovering this free blood. After the blood has been collected, washed, and packed by the cell saver system, anaerobic aerobic cultures will be obtained as well as white blood cell count, red blood cell count, platelet count, Wright stain, plasma-free hemoglobin, heparin, fibrinogen and gentamycin levels. This will be done on all collections by the cell saver. In cases where contamination of the blood by enteric contents is documented, the washed, packed red blood cells recovered will not be given to the patient. Post-operatively the patients who have received noncontaminated and washed red blood cells will be followed closely for clinical signs of sepsis. When indicated serial blood cultures will be obtained and the patient treated with appropriate antibiotics pending culture results. The wash solution used during the recovery system will contain 80 mg of gentamycin per liter of wash solution. This has been demonstrated to effectively eliminate aerobic organisms from the washed cell product as well as pathogenic anaerobic organisms. Also it has been demonstrated that the cell saver effectively removes essentially all free gentamycin from the red cell product.

PROGRESS

Revisions have been requested by the WBAMC Human Use Committee. The project will commence when these changes have been forwarded and accepted.

STATUS: Ongoing

#### APPENDIX I

Representative Training Protocols supported by the Department of  
Clinical Investigation, William Beaumont Army Medical Center,  
during FY80.

### Behavioral and Learning Theories of Crime

178

Biological Research Facility  
Department of Clinical Investigation  
William Beaumont Army Medical Center

Summary of Non-Research Supported Training Data

1. Biomedical Residents and Nurse Training	12 months
2. Resident Specialist Care Course	12 months
3. Trauma Unit and COTW Med Eval	12 months
4. Gastroenterology Residents Major Surgical Procedures	12 months
5. Surgical Staff and Residents Major Surgical Procedures	12 months
6. Surgical Staff and Residents Microvascular Surgical Procedures	12 months

# DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is The Adjutant General's Office.

REFERENCE OR OFFICE SYMBOL	SUBJECT
	Training Protocol

TO	FROM	DATE	CMT 1
1HR C, Clin Invest Svc	Neonatal Svc	1 Dec 1979	

20 C, Bio Research Facility

1. Request the use of the Biological Research Facility for the purpose of training professional and paraprofessional staff members of the neonatal service. The objective of the training is to familiarize the staff with the indications and techniques for endotracheal intubation and chest tube insertion.

2. Equipment Required:

a. Lab animals

- (1) 1 kitten per session - intubation
- (2) 1 rabbit per session - chest tube insertion

b. Laryngoscope with blade

c. 3.0 mm endotracheal tube

d. Argyl chest tube with trocar

e. Underwater Seal

f. Appropriate anesthetic agents

g. Veterinary supervision and expertise will be required for preparing the lab animals and assistance in teaching the staff.

h. Approximately 6 classes will be required (1 class per week) with four persons per class.

R. E. HEATH, M.D.  
MAJ, MC  
C, Neonatal Svc

# DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGCEN.

REFERENCE OR OFFICE SYMBOL

SUBJECT

ATZC-MDOG

Use of Biologic Research Facilities for Training

XP

THRU

LTC L. L. Penney, MC  
C, Clin Invest Svc

FROM

LTC W. C. Daniell, MC  
Dep of OB-GYN

DATE

6 Nov 79

CMT 1

TO

CPT Gerald W. Parker, Jr., VC  
Asst C, Bio Rsch Section

1. Request the use of your facility on 29 Nov 79 and 13 Dec 79, from 0800 to 0900 hrs, for the purpose of training OB-GYN residents in techniques for intubation.
2. We will require two anesthetized cats, a veterinarian for supervision, and appropriate endotracheal tubes and laryngoscopes.

*W. C. Daniell, M.D.*

WALTER C. DANIELL, M.D.

Lt. Colonel, MC

Chief, Perinatology and  
Obstetrics Services

Department of Obstetrics & Gynecology



# DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGCEN.

REFERENCE OR OFFICE SYMBOL

SUBJECT

ATZC-MDPE

Pediatrics and Obstetrics House Staff Training

TO Clinical Inves Svc

FROM

C, Neonatal Svc

DATE 3 Jul 80

CMT 1

ATTN: C, Biological Research

Dr Leonard/mmr/2249

1. The objectives of this program are to familiarize the Pediatrics and Obstetrics house staff with indications, outcome, and equipment related to endotracheal intubation, chest tube insertion, and venous cutdown.

2. We request the use of your facility starting 15 July 1980 from 0900 to 1100 hours. This teaching exercise will be held weekly. Termination date - 16 September 1980.

3. Laboratory animals - equipment

a. Endotracheal intubation - 1 kitten

b. Chest tube insertion and cutdown - 1 rabbit

c. 2 Venesection trays

d. Laryngoscope with blade

\*e. Endotracheal tubes 3.0 mm or 18 French

\*f. Argyle chest tubes with trochar and Rob Nel Catheters (10 and 12 French)

g. Underwater Seal

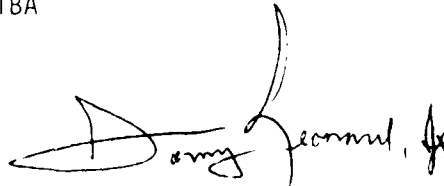
\* Supplies provided by Newborn Medicine Service.

4. Participants

SCHEDULE - 0900 - 1100 HOURS

15 July	Dr Tremper	Dr. P. Muelenaer
22 July	Dr Baugh	Dr Matson
29 July	Dr Crowe	Dr A. Muelenaer
5 Aug	Dr Egerton	Dr Rawlings
12 Aug	Dr Carrion	Dr Walker
19 Aug	Dr Pereira	Dr Covarrubias
26 Aug	Dr Stafford	Dr Hill
2 Sep	Dr Chikanchi	Dr Lawrence
9 Sep	Dr Woodruff	**TBA
16 Sep	**TBA	**TBA

\*\* To be assigned



TOMMY LEONARD, JR., M.D.

MAJ, MC

C, Neonatal Service

182

DA FORM 2496

REPLACES DD FORM 96, WHICH IS OBSOLETE.

☆ U.S. G.P.O. 1976-666-97-1

# DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGCEN.

REFERENCE OR OFFICE SYMBOL	SUBJECT
ATZC-MDDS	Inservice on Airway Management and Intubation
to Bio-Research Laboratory	FROM C Resident, Trauma Svc
	DATE 8 Sep 80 CMT 1
	CPT Camunas/sl/2698

1. An inservice will be carried out on airway management and intubation in the Bio-Research Laboratory. There will be 14 persons from the Trauma Unit and 507th Med-Evac unit participating in the inservice. The inservice will be supervised by Chief of the Bio-Research laboratory and chief resident of the Trauma Unit.
2. The inservice will be held on Thursday, 11 September 1980 at 1430 hours in the Bio-Research Laboratory of William Beaumont Army Medical Center.

*Joseph A. Camunas*  
JOSEPH A. CAMUNAS, MD  
CPT, MC  
Chief Resident, Trauma Service

1. *Per verbal agreement: Two sessions instead of one large group.*
- |                          |                  |
|--------------------------|------------------|
| <i>11 Sept, 1230 hrs</i> | <i>7 persons</i> |
| <i>18 Sept, 1430 hrs</i> | <i>7 persons</i> |

*Berny Parker*

# DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is The Adjutant General's Office.

REFERENCE OR OFFICE SYMBOL

ATV-AMOM-GE

SUBJECT

TRAINING PROTOCOL

TO

Dr. Fenner

FROM

Dr. Fenner- Gastro

DATE

24 Sept

CMT 1

PROCEDURE-- ERCP (Endoscopic Retrograde Cholangiopancreatogram). This is cannulation of the Ampulla of Vater and injecting a contrast agent to outline the pancreatic duct and biliary system.

ANIMAL-- Beagle--two dogs each session

TIME-- Every Friday 1300-1500 hrs

EQUIPMENT--available in Gastroenterology Clinic

ANESTHESIA-- General

SPECIAL INSTRUCTIONS-- Animals will have to be NPO after midnight Thursday night except they may have water for breakfast on the day of the procedure. The animals will also be given Robinul during the procedure to decrease intestinal motility.

REASONS FOR REQUEST-- To enable Gastroenterology Staff and Fellows to become more proficient at performing ERCP.

Personnel--Gastroenterology Staff and Fellows. Personnel in Animal Laboratory Section.

David K Fenner  
David K. Fenner M.D.  
Major MC  
Gastroenterology Staff

5 Oct 27 1 dog

1. **ATTENTION** **FILE** **11**

2. **ATTENTION** **FILE** **11**

3. **ATTENTION** **FILE** **11**

4. **ATTENTION** **FILE** **11**

5. **ATTENTION** **FILE** **11**

6. **ATTENTION** **FILE** **11**

7. **ATTENTION** **FILE** **11**

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11. **ATTENTION** **FILE** **11**

12. **ATTENTION** **FILE** **11**

13. **ATTENTION** **FILE** **11**

14. **ATTENTION** **FILE** **11**

15. **ATTENTION** **FILE** **11**

16. **ATTENTION** **FILE** **11**

17. **ATTENTION** **FILE** **11**

1. Use of the Bio-Medical Research Facility and its staff is posted each Friday afternoon from 1215-1330 hours for training students from the Patient Care Specialist Course, WEAMC, in CR scrub, gown and glove technique, and in minor suturing technique, in the demonstration and IE in intubation.

2. Or scrub greens and sterile gowns will be provided by the RSCC instructor.

3. Groups consist of 4-6 students. The groups will be in the facility as indicated below.

4. Equipment: Minor suture pack (suture 3-0 silk with needles sterile drapes) gloves pr. 6, shoes (booty conductive), hats.

5. Manpower requested: 2 Vet specialist, 1- Vet. (VC) specialist- (anesthesia, scrub), V.C. - supervisor

6. Request 1 (one) canine, dog, for the suture procedure.  
Request 1 (one) feline, cat, for the intubation procedure.

DATES	GROUP	LOCATION
11 Aug ✓	3	ENC
12 Aug ✓	4	"
13 Aug ✓	5	"
14 Aug ✓	6	"
15 Aug	7	"
16 Aug	1	"
17 Aug	2	"

*W. G. Beckwood*  
W. G. Beckwood

W. G. Beckwood

W. G. Beckwood

# DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is The Adjutant General's Office.

# 6

REFERENCE OR OFFICE SYMBOL	SUBJECT
ATZC-MDDN-EC	Use of the Bi-Medical Research Facility

TO	FROM	DATE	CM: 1
Dr. Parker CPT VC OIC, Bio-Med Res Fac	Director PCSC WBAMC	12 Feb 62 MPT/and/for 12 Feb 62	

1. Use of the Bio-Medical Research Facility and its staff is requested each Tuesday afternoon from 12:30 hours to 1500 hours for training students from the Patient Care Specialist Course, WBAMC, in OR scrub, gown and glove technique, and in minor suturing technique, in the demonstration and PE on intubation.
2. OR scrub greens and sterile gowns will be provided by the PCSC instructor.
3. Groups consist of 4-6 students. The groups will be in the facility as indicated below.
4. Equipment: Minor suture pack (Suture 3-0 silk, needles, sterile drapes), gloves 6 pair, shoes (booty conductive), hats.
5. Manpower requested, 2 Vet. specialist, 1 Vet. (VC)-- specialist (anesthesia, scrub), V.C. (supervisor)
6. Request 1(ONE) canine, dog, for the suture procedure.  
Request 1(ONE) feline, cat, for the intubation procedure.

DATES	GROUP	ROTATION
26 Feb.	1	RR
13 March	1	RR
8 April	2	RR
29 April	3	RR
20 May	4	RR
19 June	5	RR
1 July	6	RR

Lynn C. Blackwood  
MAJ, MC  
Director PCSC

# DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGCEN.

REFERENCE TO OTHER FORMS

17

ALIC-400S-GH

Surgical Autostapling Devices

TO C, Clinical Investigations  
LTC Penney

FROM Urology Service  
WBAMC

DATE 19 Jan 1980

CW

We are requesting the use of the animal research facilities on Thursday, 17 Jan, at 1300 hours for the purpose of demonstrating and exercising the use of surgical autostapling devices. Please inform us if this will be convenient.

Respectfully submitted,

*Fernando Diaz-Ball*

FERNANDO DIAZ-BALL, M.D.  
COL, MC  
Asst Chief, Urology Service

*Thomas J. Vane*  
THOMAS J. VANE, M.D.  
CPT, MC  
Resident

From: Urology Service

From: C, Biological Research Center, WBAMC  
17 Jan 80

1. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.  
2. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.  
3. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.  
4. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.  
5. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.  
6. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.  
7. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.  
8. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.  
9. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.  
10. Request for use of animal research facilities on Thursday, 17 Jan, at 1300 hours.

*Gerald W. Turner*  
Gerald W. Turner, DVM  
CPT VC  
C, Biological Research Center

# DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGCEN.

REFERENCE OR OFFICE SYMBOL

SUBJECT

ATZC MDDS PVS

Use of Dogs in Biological Research

TO Dir, Biological Research Svc FROM C, Peripheral Vascular DATE 16 Jun 80 CMT  
Clinical Investigations Svc Surgery Service LTC Collins/jc 2621  
(ATTN: Dr. Parker) Director, Trauma Ctr

1. This is to confirm our previous discussion regarding the use of two dogs for studying the technique of rectal ~~anal~~ <sup>anal</sup> replacement and preparation for performing the same procedure on human beings. As we discussed, we would like to use two dogs, one on Monday, 16 June 1980, and the second dog at the convenience of your service and mine. The training opportunity provided by your unit is most appreciative and should significantly enhance the potential for a successful procedure on our human patients.

2. Thank you very much for your support in this regard.



JOHN T. COLLINS, JR., M.D.  
LTC, MC  
Chief, Peripheral Vascular Surgery Svc  
Director, Trauma Center

# DISPOSITION FORM

For use of this form, see AR 340-13, the proponent agency is TAGCEN.

REFERENCE OR OFFICE SYMBOL

SUBJECT

ATZC-MDDS-GSS

Use of Dog Lab Facilities and Canine

TO Clinical Investigation Div FROM C, Gen Surg Svc

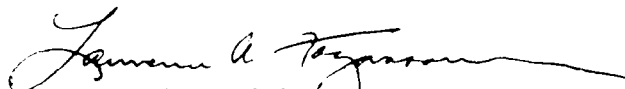
DATE 30 July 1980 CMT 1  
COL Fagarason/sl/2698

1. Request the use of the Clinical Investigation Dog Lab facilities and the use of a canine subject for training protocol as follows:

Object: The perfection of technical skill in placement of the Hunter-Sessions vena caval occluder (intra-vascular balloon device)

Method: In an anesthetized canine subject a cut-down over the right internal jugular vein and a venotomy through which the vena caval occluding balloon can be placed in an intra vena caval position. Fluoroscopic capability is requested in order to ascertain proper positioning of the balloon below the renal veins. It is anticipated that the balloon will be retrieved from the experimental animal, thus permitting salvage of the subject animal.

2. Request definitive information as to date and time that this teaching/learning endeavor can be performed.

  
LAWRENCE A. FAGARASON, MD  
COL, MC  
Chief, General Surgery Service



# DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is The Adjutant General's Office.

REFERENCE OR OFFICE SYMBOL

SUBJECT

Training Protocol

NO

FROM

DATE

CMT 1

C, Dept Clin Invest

Peripheral Vascular Svc

23 June 1980

C, Bio Research Fac

Request the use of the Biological Research Facility for the purpose of training clinical residents in the techniques of performing Aortic bypass Graft procedures. This training can be accomplished in conjunction with your surgery schedule for the previously approved research protocol #80/12. Additional animals and supplies are not required.

This will be an excellent opportunity to provide vascular surgical training while simultaneously conducting a research endeavor, thus minimizing animal utilization, supplies, and maximizing personnel time.

JOHN T. COLLINS, JR. M.D.  
LTC, MC  
C, Peripheral Vascular Svc

# DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is The Adjutant General's Office.

REFERENCE OR OFFICE SYMBOL

SUBJECT

Training Protocol

TO

FROM

DATE

CMT 1

THRU C, Dept Clin Invest

Peripheral Vascular Svc

1 August 1980

TO Biological Research Facility

1. In reference to our previous discussions of the Hemodynamics Cell Saver System, it is requested that the lab animal surgical facility be available for demonstration of the equipment. The objective will be to demonstrate and train selected individuals in the trauma unit on the use of the Cell Saver System. This can be accomplished on an animal that is undergoing an Aortic bypass graft procedure in the previously approved research protocol #80/12. Additional animals will not be required for this training endeavor.

JOHN T. COLLINS, JR. M. D.  
LTC, MC  
C, Peripheral Vascular Svc

AD-A099 120

WILLIAM BEAUMONT ARMY MEDICAL CENTER EL PASO TX  
ANNUAL PROGRESS REPORT, FISCAL YEAR 1980.(U)  
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7 APR 80



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DATE  
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# DISPOSITION FORM

For use of this form, see R 140-13; the proponent agency is The Adjutant General's Office.

REFERENCE OR ORIGIN	SUBJECT
	Microvascular Surgical Training

THRU	C, Dept Clin Invest	FROM	Plastic Surgery Svc	DATE		CMT 1	
TO	C, Bio Research						

1. The plastic surgery service request the use of the Biological Research Facility for the purpose of training the staff and residents in the techniques for performing microvascular surgical procedures.
2. The use of the surgical facility, operating microscope, microsurgical instruments, and one animal (rat) per session will be required. The procedures will consist of various arterial and venous anastomosis. An appropriate general anesthetic will be required for the animal.
3. It is anticipated that three, two-hour sessions per week will be required. One or two surgeons will be present at each training class.

Chief, Plastic Surgery Service

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